University of Alberta

A Child of One's Own: Assisted Reproductive Technologies and Law in Canada

by

Katherine Mary Cherniawsky

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfilment of the requirements for the degree of Master of Laws.

Faculty of Law

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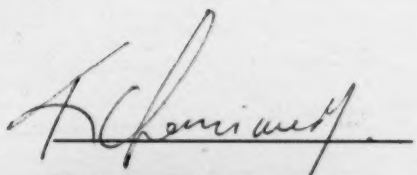

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled *A Child of One's Own: Assisted Reproduction and Law in Canada* by Katherine Mary Cherniawsky in partial fulfilment of the requirements for the degree of Master of Laws.

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ABSTRACT

The objective of this thesis is to examine the law applicable to assisted reproductive technologies from the context of patient/physician relationships. First, it provides background about the science of assisted procreation and the interested parties. Next, it examines the five layers which form the existing Canadian legal landscape: common law principles applicable to patient/physician relationships; relevant constitutional considerations, including a constitutional right to assisted procreation; historical evolution of health care policy in Canada; statutory enactments and proposals specific to assisted reproductive technologies; and, jurisprudence specific to assisted reproductive technologies. Then, significant Canadian law reform studies and foreign statutes are examined with a view to deciphering common elements and alternative policy models for Canada. Finally, the thesis draws upon these materials to analyse the merits of three policy models: criminal models; *laissez faire* professional self regulating models; and, regulatory models. This thesis suggests that a regulatory model is the best means to both capture the benefits and avoid the harms of this technology. It provides a guide for the construction of a regulatory legislative overlay to existing Canadian laws.

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AUTHOR'S NOTE

Assisted reproductive technology is a rapidly evolving and well publicised science. This thesis attempts to capture Canadian legal developments up to March 1, 1999. Since that time two significant events occurred. First, the Supreme Court of Canada released its decision in *M. v. H.* ((20 May 1999) No. 25838 (S.C.C.)) affirming the Ontario Court of Appeal ruling that the failure of provincial family law legislation to extend support right to same sex couples violates section 15 of the *Canadian Charter of Rights and Freedoms.* Second, the Minister of Health affirmed that legislation to replace Bill C-47 would be reintroduced before the end of the year. While details remain sketchy, the law is expected to be quite comprehensive and to include criminal prohibitions; national standards and a federal body to regulate and license facilities providing fertility treatments and embryonic research.

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CHAPTER ONE: *A Child of One's Own - Assisted Reproduction Then and Now*

> Emerging technologies that increase procreative control are lending support to the view that society has not only the authority but the duty to intervene in reproductive decision making. Whether out of concern for the affected children, future generations, the health of the gene pool, or some other good, there is evidence of a gradual shift to the viewpoint that some constraints ought to be placed on human reproduction when individuals abuse those rights. Even though procreation is an inalienable right, it can be regulated by a society that is concerned with the existence of each child and with its own survival. Reproduction, according to this view, is a right shared with society as a whole and is part of a larger complex of rights, responsibilities, and obligations. State intervention might be justified under certain circumstances; each case must be analysed carefully.[1]

The desire for a child and the instinct to pass on one's genetic heritage are central to human existence. The decision to procreate is deeply personal. Despite intensely personal aspects, this decision (if it involves assisted reproductive technology) may also have far reaching and unique effects upon others, particularly in states committed to providing universal medical and social care systems. Assisted reproduction often involves the use of extremely capital intensive technologies for the benefit of small groups of patients in controversial ways that some perceive as miraculous and others as medically unnecessary or unethical. Scientific advances in human reproduction enable divergence from the historical coincidence of sexual activity and human reproduction. Used in conjunction with genetic advances, new reproductive technologies ("NRTs") also known as assisted reproductive technologies ("ARTs")[2] reduce and eliminate some aspects of the randomness of natural genetic patrimony. These new technologies also carry greater potential for conflict by bringing third parties into the reproductive decision making process, an area formerly dominated by the two genetic

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[1]R. Bank & J. Merrick, *Human Reproduction, Emerging Technologies and Conflicting Rights*, (Washington: Congressional Quarterly Inc., 1995) at 14.

[2]The terms will be used interchangeably throughout this thesis.

parents. The procedures can challenge established family institutions and configurations.[3] Many governments have responded to these developments with legislation. However, while the novel situations created by ARTs raise difficult and divisive issues, it is less clear that they also create a need for unique statutory intervention.

A. Medical Treatments and The Desire for A Child in 1978

A person experiencing infertility or some other obstacle to sexual reproduction in 1978 would probably have sought assistance from a physician.[4] In the 1970's, potential treatment options included fertility drugs and artificial insemination. Other techniques such as *in vitro* fertilization and cloning, were considered highly experimental, a distant dream viewed by the public with skepticism and suspicion. This dream was realized in part with the birth of Louise Brown in England.[5] Until that point, legal conflicts regarding human reproduction had generally focussed upon the right **not** to reproduce rather than the right to procreative assistance.[6] Difficult issues such as access to treatments, externally imposed limits on

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[3]Many Canadian law reform studies adhered to a narrow definition of family that greatly affected the scope and content of legal recommendations concerning ARTs. Despite popular notions regarding family, traditional family relationships and values vary so greatly over time and from place to place that this notion has no universal meaning, see generally S. Kelman, *All in the Family* (Toronto: Penguin Group, 1998).

[4]Although some forms of self-insemination may be achieved without medical assistance.

[5]After several unsuccessful attempts, Louise Brown was born weighing 5 pounds and 12 ounces on July 25, 1978 with the assistance of Drs. Edwards and Steptoe. While the furor over this success grew, reporters were also writing about physicians in the United States who had also attempted to create excorporeal embryos, the results of which were later destroyed against the wishes of the commissioning couple, Mr. and Mrs. Del Zios: see A. Bonnicksen, *In Vitro Fertilization Building Policy from Laboratories to Legislatures* (New York: Columbia University Press, 1989) at 16-18. Procedures enabling the fertilization and long term maintenance of human embryos outside of the body did not become widely available for some years. Techniques to preserve human ova at low temperatures are now becoming available.

[6]With the exception of conflict over nonconsensual sterilization. For a complete discussion of laws and gender bias concerning the procreative function of women's bodies see S. Martin, *Legal Controls on Human Reproduction in Canada: A History of Gender Biased Laws and the Promise of the Charter* (Doctor of Juridical Science,

treatment, eugenics and the custody of preserved gametes and embryos had not yet captured a level of popular attention sufficient to prompt the promulgation of statutes specific to assisted reproduction.

In Canada, seeking reproductive assistance was a medical matter negotiated privately between patients and physicians, within the context of a publicly financed, comprehensive health care system. Neither party was subject to specific legislation. While some jurisdictions had enacted a few fragmentary provisions of note, those provisions were mainly aimed at protecting the rights of living children conceived through ARTs.[7] The laws were designed to put children of artificial reproduction in the same legal position as those conceived through sexual reproduction with respect to family and estate matters. No statutes had been enacted to regulate the provision of ARTs or to govern an affirmative entitlement to reproduce.

B. Medical Treatment and The Desire for A Child in 1999

Treatment options available to patients seeking assisted reproduction services in 1999 have ballooned due to a greater understanding of reproduction and embryonic development. Cumulative scientific advances have made the human fetus, from its earliest stages, more familiar and human.[8] In some instances it is seen as an entity in conflict with its environment, the gestating mother. During the past 20 years, amazing genetic breakthroughs have occurred,

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Thesis, University of Toronto, 1991).

[7]See for example *Children's Act*, S.Y.T. 1986, c.22, s.14, discussed in chapter 3, below.

[8]However, the fetus is not a legal entity. Under Canadian law live birth is necessary to trigger legal rights *Winnipeg Child and Family Services (Northwest Area) v. D.F.G.*, [1998] 1 W.W.R. 1 (S.C.C.)

particularly regarding the early detection of genetic abnormalities, diseases, and propensities for diseases. These genetic advances have profoundly impacted ARTs in both expected and unexpected ways.[9] Individuals in the same position as the 1978 patient (and perhaps even the very same patient),[10] are likely to have enhanced treatment choices and a higher expectation of successfully realizing a child of their own.

While still a minute proportion of total births, tens of thousands of children have been born through ARTs over the past two decades.[11] In 1999, the first Canadians born through IVF, twins from Oakville, Ontario turned 17.[12] Live births as the result of ARTs are no longer an anomaly. The "children of choice" and "test tube babies" are subject to much less speculation about their "humanness." In 1999, such speculation has been reserved for the new medical enigmas - human clones and genetically engineered children. In many places, assisted reproduction is a well-established commercial industry, although the provision of treatment

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[9]The relationship of these new scientific breakthroughs in the area of gene therapy to fertility treatments are discussed in chapter 6 of Bank & Merrick, *supra* note 1.

[10]See R. Paulson & M. Sauer, "News and Views: Reproductive Health Care Policies Around the World: Regulation of Oocyte Donation to Women Over the Age of 50: A Question of Reproductive Choice" (1994) 11 J. of Assisted Rep. & Genetics 177.

[11]By the early 1980s a Federal Commission found that artificial insemination was offered at more than 18 Canadian clinics resulting in 1500 births, and demand was growing. See *Storage and Utilization of Human Sperm Report of the Advisory Committee to the Minister of National Health and Welfare* (Ottawa: Health and Welfare Canada, 1981) App. II. By the 1990s, artificial insemination was offered through 24 Canadian programs and also by family practitioners and obstetricians. In 1991, 3400 women used these services and it was estimated that between 1500 and 6000 children were born each year from artificial insemination and 400 were born from *in vitro* fertilization, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technology* (Ottawa: Minister of Government Services Canada, 1993) at 435. The Commission is hereafter referred to as the RCNRT.

[12]The first Canadians born through *in vitro* fertilization were the Rankin twins. The boys were conceived in England by the same physicians involved in the birth of Louise Brown. See A. Rochon Ford, " A Socio-Historical Examination of the Development of *In Vitro* Fertilization and Related Assisted Reproductive Techniques," in *Research Studies of the Royal Commission on New Reproductive Technologies - Treatment of Infertility: Assisted Reproductive Technologies*, vol. 9 (Ottawa: Minister of Supply and Services, 1993) 75 at 89-90.

has remained shrouded in secrecy. The provision of these services is firmly entrenched within the monopolistic control of the medical profession.[13] Medical specialists have laid claim to this urgent and growing medical need and to the exclusive right to provide solutions for infertile individuals seeking to restore their bodily functions and for others seeking assistance for diverse reasons.[14]

These novel reproductive techniques have also captured widespread public attention through sensational media reports of celebrity use,[15] medical breakthroughs such as the delivery of viable septuplets[16] or the creation of clones,[17] and the bitter legal disputes and human fall out

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[13]See J. Langton, "American Doctors Selling Made-to-Order Embryos" *The Edmonton Journal* (December 1, 1997).

[14]See Bonnicksen, *supra* note 5, discussing the evolution of fertility services as a medical sub-specialty in the United States. The definition and the estimates of the prevalence of infertility have varied over time. The RCNRT determined that for 1991-1992 8.5% of cohabiting couples failed to conceive after 1 year of intercourse without the use of contraceptives while 7% (250,000) of them had failed to conceive after a second year. The RCNRT also concluded that the rates in the United States and Canada were not rising, but that at any given time in Canada a quarter of a million couples were affected by infertility. These figures almost doubled to 15.4% and 13.2% respectively if sterilized couples were excluded from the total sample, see *Proceed with Care, supra* note 11 at 179-198. The Congress of United States Office of Technology Assessment offered similar statistics for the mid 1980s in *Infertility: Medical and Social Choices* (Washington, D.C.: U.S. Gov't Printing Office, 1988) at 35 - 58.

[15]K. Byers, "Infertility and In Vitro Fertilization - A Growing Need for Consumer-Oriented Regulation of the In Vitro Fertilization Industry" (1997) 18 J. of Leg. Med. 265 at 283-283 reviews the publicised use of ARTs by well known celebrities.

[16]The miraculous birth of the seven McCaughey babies was widely reported, often as front page news. The story made the cover of the December, 1997 issues of *Time* and *MacLeans*. Bobby McCaughey was prescribed fertility drugs due to difficulties in conceiving her first child. The case brought mixed reactions and reignited calls for regulation and concerns regarding the safety of all infertility treatments.

[17]Cloning has been very contentious with interest in it peaking at various times over the past 20 years. In 1997 the furor was over Dolly, a sheep cloned in the United Kingdom after more than 200 unsuccessful attempts. Later that year, the focus turned from sheep to people with certain doctors espousing a desire to clone human beings, see e.g. P. Kendall & R. Kotular, "Dr. Seed's Strange Love of Cloning" *Chicago Tribune* reprinted in *the Edmonton Journal* (January 10, 1998) H2. The article describes the plans of a physicist bent on cloning human beings on demand. See also P. Hopkins, "Bad Copies - How Popular Media Represent Cloning as an Ethical Problem" (1998) 28:2 Hastings Centre Report 6 discussing interaction between media, public perception and regulation.

of assisted reproduction or family relations gone wrong.[18] With the technological advancement and applications of ARTs, the public has become concerned with participants' motives and contingencies in addition to technical feasibility. These developments have also made potential recipients more informed and more likely to seek ARTs. In 1999, patients are far more attuned to the issues connected with receiving reproductive treatments and also more inclined to think differently about their own reproductive materials. However, they remain at an information deficit in comparison with the providers of such services; and the desire for a child of one's own will remain their overriding concern, a concern which may obliterate all other issues. In short, patients have higher expectations that their previously impossible aspirations may be realizable through medical miracles - hope not only for a child, but hope only for a child with specific attributes.[19]

Certain segments of the public such as potential parents, patient and consumer advocates, professional groups and other interest groups have also become more interested in these procedures. These groups view ARTs from diverse perspectives. Some extol them as a welcome cure to an epidemic. Others are more sceptical, arguing that the need for children is purely social and that the procedures themselves offer illusionary choices and false hopes. These sceptics denounce the frequently futile procedures as an inefficient use of resources which cannot be justified on a cost/benefit analysis. There are also strongly held views that

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[18]See e.g. A. Capron, "Too Many Parents" (1998) 28:5 Hastings Centre Report 22; "Octuplets - a Tragedy on the Front Pages: A Publicity Dream Dies as British Mother Miscarries the Last One on Wednesday" *the Edmonton Journal* (October 3, 1996) A17.

[19]For a discussion of the "fallacy of choice" see A. Westley, "The Myth of Designer Babies" (1996) March Policy Options 21.

artificial reproduction is immoral for various reasons: it undoes the traditional coincidence of parenthood and sexual activity jeopardising the traditional family architecture; it leads to the further suppression of women through male dominated interventions offered under the guise of enhanced choices; and, it assaults human dignity and commodifies human beings.

Scientific advances and increased public interest have not gone unnoticed by governments and other regulatory agencies. Legislative authorities have studied ARTs extensively, scrutinizing the many permutations and combinations of available and potential treatments in addition to the diverse ethical principles involved in human reproduction. These studies vary greatly in almost every sense from scope, to methodology, to final recommendations.[20] This complex collection reveals a great deal of consensus about some overarching principles: human dignity is a revered value; human reproduction is a special process; and the potential for human life and personhood embodied in the embryo is both unique and deserving of respect.[21] Most agree that human embryos and gametes have moral value as the vital source of new human life and also that human life should be afforded dignity and respect. However, a consensus about the practical translation of these broad principles into appropriate statutory enactments has been more elusive.

The application of those overarching principles to the patient/physician relationship has

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[20]The evolution and expansion of issues can be seen in the contrast of Scottish Home Dept., *The Report of the Departmental Committee on Human Artificial Insemination* (London: Her Majesty's Stationery Office, 1960) with the *Report of the Committee of the Inquiry Into Human Fertilisation Embryology* (London: Her Majesty's Stationery Office, 1985) or the 1992 RCNRT report *Proceed with Care, supra* note 11.

[21]S. LeBris & B. Knoppers, "Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues" (1991) 17 Am. J. of L. & Med. 329.

yielded vastly different legal responses.[22] Some governments welcomed the advances of the last 20 years, while others condemned them. Some intervened in the course of scientific progress and treatment of patients, while others adopted a *laissez-faire* approach leaving controls and safeguards on the scientific imperative to the medical profession and to individual choice. In the latter jurisdictions, no ART specific laws have been enacted - disputes over the treatment or denial of treatment have been left to incremental resolution through existing laws and administrative and judicial authorities. In other jurisdictions, legislative initiatives have been minimal, limited to discrete issues such as the legitimacy and inheritance rights of artificially conceived children or the screening of gametes for communicable diseases in the interests of public health. In these places, the provision of services has also been left to the control of the medical profession. By contrast, at the interventionist end of the spectrum, governments have altered the usual role of physicians and their professional associations through the enactment of laws to vigorously regulate, or in some instances prohibit, ARTs.[23]

There is a great diversity in ART specific enactments. Some acts focus upon the rights of existing people: prospective patients, donors and providers. These schemes place paramount importance on individual liberty and build upon individual choice, rights and responsibilities. Other statutes are centred upon the presumed interests of potential offspring. Still other

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[22] See P. Baird, "Implications of Scientific Innovation in the New Reproductive Technologies" in B. Dickens & M. Ouellette, eds. *Health Care Ethics and Law* (Ottawa: les Editions Themis, 1993) 267 at 276-278 describing the ethical implications and diverse reactions to preimplantation diagnosis, total surrogacy and embryo freezing.

[23]The first of these acts, the *Infertility (Medical Procedures) Act 1984*, No. 10163, was enacted in the Australian State of Victoria in 1984. It was substantially amended in 1995 (*Infertility Treatment Act 1995*, No. 63. The 1984 act is thoroughly reviewed by L. Waller, "Australia: The Law and Infertility- The Victorian Experience,"in S. McLean, ed., *Law Reform and Human Reproduction* (Aldershot: Dartmouth Publishing Co. Ltd., 1992) 17.

systems are guided by religious doctrine. Regardless of the stated purposes or guiding principles, these acts often reveal and perpetuate strong biases about men and women, parenting abilities and obligations, entitlements and the configuration of the optimal family unit.[24] The practical choices available to the patient in 1999 will have been shaped and limited by the extent to which governments have elected to legislate with respect to ARTs. Patients seeking assistance may no longer be subject to or enjoy the benefits of the usual legal rules governing patient/physician relationships. The very existence of these acts affects their choices, rights and responsibilities in unprecedented ways. Personal issues such as their identity, residence, motivations, age, sexual orientation, living arrangements and other factors have taken on unprecedented legal significance, altering the usual patient/physician relationship as well as the range of options and likelihood of achieving their objective - a child of their own.

This thesis examines current and proposed laws applicable to ARTs in Canada. Chapter Two provides background about assisted reproduction. It introduces constituent elements of ARTs, including: basic technical terms, techniques and attendant issues, the interested parties and the overall characterization of ARTs as medical procedures. Chapter Three examines the existing Canadian legal landscape in five stages. The first part describes common law principles which govern patient/physician relationships. The second part details the constitutional parameters within which ART specific laws might be enacted. This part also considers the possibility of an entrenched entitlement to ARTs. In the third part, a brief

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[24]Martin, *supra* note 6 discusses bias in the development of spousal rape, access to contraceptives, abortion, and legal controls of the actions of pregnant women.

history of the regulation of medical care within these constitutional parameters is provided. The final parts canvass statutory enactments and cases which deal specifically with ARTs. In Chapter Four significant Canadian law reform studies addressing assisted reproduction are analysed. Chapter Five compares ART specific statutes enacted in other jurisdictions with a view to creating alternative policy models for Canada.[25] Chapter Six draws upon the materials from the earlier chapters to analyse the merits of ART specific legislation proposed by the federal government and to provide a guide for the construction of a legislative overlay to existing Canadian laws.

This thesis focuses upon statutory regulation of assisted procreation from the medical treatment perspective. Laws about other aspects of human reproduction, such as abortion, sterilization, contraception and forced intervention in pregnancy form part of the legal background and provide context for policy development. However, they are merely tangential. Similarly, laws governing other uses of human embryos and embryonic and fetal tissues and germ line therapy in general are not entirely germaine. This thesis examines ARTs in the context of medical treatment and proceeds from a legal perspective based upon interdisciplinary resources. The author possesses no medical, philosophical or bioethics training.

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[25]Several aspects of these laws will be examined including: the intensity of government intervention, the nature of the legal instrument of control; triggers of legislative intervention; the stated purposes and guiding principles of regulation; levels of patient, donor and provider autonomy with reference to access, and reporting requirements; and, other provisions related to the status of embryos and resultant children.

CHAPTER TWO: *Defining the Field*

Language in the field of assisted procreation has significant symbolic and moral qualities. It is often value laden, although these values may be hidden. ARTs often involve quite technical jargon as the medical profession has defined a majority of the key terms. Critics suggest that terms are medicalized to obviate their ethical or human value. For example, "selective reduction" euphemistically describes the procedure whereby living embryos are terminated in the interests of the remaining embryos, or because of genetic defects or for some other purpose. In other circumstances, this same procedure would be called abortion or feticide. Similarly, the terms zygote, fertilized ovum, preembryo, embryo foetus, unborn child or child can all be used to describe a developing human being. It is important to be aware of what these technical terms are actually describing and to critically assess both the underlying procedures and the descriptive language. This chapter outlines some preliminary issues. It defines some common procedures and identifies attendant issues and interested parties. The parties involved in ARTs and their basic concerns are set out in Appendix A.

ARTs encompass all treatments, techniques or services which are medical, surgical or obstetric and which are provided with the ultimate goal of impregnating a woman. ARTs also include related transactions between medical intermediaries and material donors. There are few standard legal definitions of ARTs or their constituent elements. The exact terms and coverage in law reform studies and in legislation and professional codes vary greatly over time and from one jurisdiction to another. Even the legal studies and regimes within single nations

vary greatly in content and use of language.[1] The variations make comparison difficult, but reveal much about the nature and purpose of legislation. The dynamic nature of the technology and its attendant technical language exacerbates the confusion. The law has often had difficulty keeping pace with changes in medical terminology and technology.[2] Due to the lack of linguistic consistency, certain common terms and ARTs will be defined in this chapter.

A. Defining Common Terms

Infertility is a key term, often it is the trigger of moral and legal entitlement to ARTs. It is a medical condition resulting in an unwanted reduction of reproductive capacity or the failure of a cohabiting couple to conceive after a certain period of engaging in sexual intercourse without any means of contraception. The period is sometimes set at one year, although two years is also a common measure. Infertility is often expressed as a percentage of a larger group such as the general population, couples of reproductive age or couples actively attempting to reproduce.[3] The technical definition of infertility has important consequences.

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[1]E.g., the RCNRT addressed terminology in several portions of its final report. According to the RCNRT "The term 'pre-embryo' has been a source of controversy, however, some people believe that it diminishes the humanity of the developing entity. To avoid this possible bias, we have chosen the more neutral term 'zygote'", *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technology* (Ottawa: Minister of Supply and Services Canada, 1993) at 613 [hereafter *Proceed with Care*]. The words zygote, oocyte, embryo, foetus and human being or child have all been used to describe the same entity in statutes. In the Canadian Bill C-47, *Human Reproduction and Genetic Technologies Act*, 2nd sess., 35th Parl., 1996 three terms are used to describe a developing human fetus: over the first 14 days of development it is a zygote, for the next 41 days of development it is an embryo and after 56 days it is a foetus.

[2]For example, fetal viability has traditionally been cited as a significant event justifying state intrusion upon individual legal rights in the name of the public interest. However, science is bending the concept of viability to such a degree that it may be no longer represent a defensible trigger of the public interest.

[3]The Ontario Law Reform Commission measured infertility subjectively by asking physicians to estimate the number of couples attempting to conceive who were "affected by infertility" and seeking treatment; *Report on Human Artificial Reproduction and Related Matters* (Toronto: Ministry of the Attorney General, 1985) at 10-11.The RCNRT gathered a comprehensive information about infertility and its prevalence in the 1990's and determined that at any time infertility affected 250,000 Canadians *Proceed with Care, supra* note 1 at 181-194.

As infertility is often a prerequisite of access to ARTs, its meaning determines the pool of eligible patients effectively controlling the demand for the procedures. The more inclusive the definition of infertility, the greater the perceived need for and the likelihood of public acceptance of ARTs.[4] Another incidental effect is that the larger the group of "infertile" patients, the more likely that couples who are described as medical successes will in fact have conceived naturally.

Success is another key term with no universal meaning. While the ultimate goal in assisted human reproduction is to maximize the likelihood of the birth of a healthy baby, this goal is not necessarily synonymous with success. For some providers, success means a chemical pregnancy; for others it is the creation of an excorporal embryo or an oocyte. For those seeking assistance, success is more likely to mean the safe delivery of a healthy infant. The definition of success was considered to be so important by the Federal Government of the United States that Congress enacted national standards to control the use of this term and to ensure that users and providers were speaking the same language.[5] Canadian reform commissions have also recommended a standardized definition of success that is meaningful to potential ART recipients.

Artificial insemination ("AI") is the oldest and most simple form of assisted reproduction.

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[4]Individuals who "suffer" from infertility and those with genetic defects or disabilities are frequently categorized as more worthy recipients. Commissions often limit discussion to these groups and create a circular justification for placing assisted procreation within the politically significant category of medically required services.

[5]*The Fertility Clinic Success Rate and Certification Act of 1992*, 42 U.S.C. ss. 263a (1) - (4), the act is discussed below in chapter 5. See also R. Stenger, "The Law and Assisted Reproduction in the United Kingdom and the United States" (1994-5) 9 J. of L. & Health 135.

It involves the intravaginal or intrauterine placement of semen using a mechanical device. It requires the least capital or technical expertise. AI can be achieved without medical supervision. AI is used to overcome physical limitations, male infertility, the absence of a male partner or the risk of transmitting genetic diseases or defects. Semen may come from the partner or spouse of the recipient, or from known or anonymous donors.[6] It is a highly successful procedure relative to other ARTs as the recipients often have no additional impediments to fertility. AI separates biological parenthood from social parenthood. Infectious and genetic diseases may be transmitted by this procedure. The issues raised by AI include appropriate limits on access, whether AI constitutes adultery, allocation of legal responsibility over resultant children, potential liability of professional intermediaries and the flow of information between donors and offspring.

***In vitro* fertilization** ("IVF") is the extracorporeal fertilization of ova which, once fertilized, are transferred into a woman's uterus. The fertilized ova may be returned to the original source or placed in another woman. In the later case, the term **embryo transfer** is frequently used to describe the procedure. IVF is used to overcome female or male infertility, lack of a female partner or menopause and to prevent the transmission of genetic disease or defects. IVF separates fertilization from gestation and physical custody. It results in the existence of an extra corporeal being with the potential to develop into a human being. The procedure also enables a woman who is not genetically related to the embryo to gestate the embryo and deliver the baby. Side effects of IVF include the inadvertent transmission of infectious and

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[6]For a description of various types of AI classified on the basis of material origin, material placement or method of insemination see *Proceed with Care*, *supra* note 1, chapter 19 and especially at 432.

genetic diseases, medical risks involved in retrieving eggs, a high incidence of multiple order births and adverse effects of fertility drugs used to induce egg production. Like AI, IVF raises issues about access to treatment, professional liability, parental rights and the alienation and subsequent use of gametes. IVF also raises issues about the moral and legal status of extra corporeal embryos. **Zygote intra fallopian transfer ("ZIFT")** is a form of IVF in which zygotes created *in vitro* are later placed in the fallopian tubes of the recipient.

Gamete intra fallopian transfer ("GIFT") involves the removal of eggs and the subsequent placement of those eggs together with sperm into the fallopian tubes where fertilization and gestation later occur. While the embryo is created solely within a woman's body, the woman need not be the original donor. GIFT raises many of the issues raised by IVF and ZIFT. Medical risks associated with the procedure are similar to those for other surgical procedures involving donated materials and anaesthetics.

Intra Cytoplasmic Sperm Injection ("ICSI") is a newer variation of IVF. ICSI significantly raises the chances of fertilization as sperm are physically injected into ova. ICSI is used to improve IVF success rates or to treat severe male factor infertility and produce a child genetically related to both intended parents. The recipient "patient" may possess fully normal fertility functions. As the embryo is genetically related to the parties, it raises fewer issues than some other types of IVF. However, ICSI may carry a higher risk of birth defects or genetic defect or disease depending upon the cause of the male infertility.

Cryopreservation is the preservation of reproductive materials at very low temperatures. The

frozen materials can be maintained in a suspended state for years and then heated and allowed to mature. This reduces the costs of IVF and the need to undergo repeated hormone treatments as several embryos can be created at one time and preserved for later use. Currently sperm and embryos can be reliably frozen. While the maintenance of unfertilized eggs is possible, they are more fragile and more likely to be damaged by cryopreservation. The ability to maintain gametes and embryos in perpetuity breaks the natural structure of human generations, separates gestation and physical custody for potentially unlimited periods of time exacerbating the issues raised by IVF, particularly issues concerning the relative rights of alienation and control over the preserved embryos as asserted by parents, providers and others.

Fertility drugs are usually prescribed by family practitioners, obstetricians/gynaecologists or fertility specialists to induce ovum production. They are the most common form of infertility treatment. The drugs are used either alone or along with other ARTs to improve the overall chances of success.[7] If more than one woman is involved in creating a child, then both may receive drugs to harmonize their cycles and improve the chances of successfully transferring a pregnancy. Pharmaceutical companies produce and market fertility drugs just like any other pharmaceutical product. These drugs alter the woman's usual reproductive cycle and carry many side effects and risks including a high risk of multiple order births, an increased risk of certain cancers, hot flushes, bloating, abdominal pain, dizziness, sleeplessness, anxiety, depression and moodiness. The prevalence and severity of these side effects are unknown.

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[7] In *Proceed with Care*, *supra* note 1 at 387-423 and at 393-403 the RCNRT outlined the main types of female and male fertility drugs.

Surrogacy agreements are also known as preconception agreements or gestational contracts. Under these agreements a woman (the surrogate) agrees to gestate and bear a child on the understanding that it will be raised by others (the commissioning couple). Custody and guardianship are transferred to the commissioning couple through adoption or agreement. Surrogacy can be used in conjunction with AI or IVF. The surrogate need not provide her ovum. If she does, the surrogacy is described as genetic surrogacy. If the surrogate mother is not genetically related to the child then the agreement is described as total surrogacy or gestational surrogacy. Under a commercial arrangement the commissioning couple pays expenses plus fees to the surrogate and to any intermediary broker. Noncommercial arrangements do not involve fees, only expenses are reimbursed. Such agreements are often made amongst family members or friends. Surrogacy can be used to overcome medical or physical conditions which make pregnancy impossible or dangerous for the intended mother, to avoid environmental risks to the child or for nonmedical reasons.[8] Surrogacy separates genetic and social parentage and also separates the defining female function, gestation, from parentage. It raises issues about control over one's own body and the potential for coercion amongst family members, friends and strangers. Key legal issues surround the validity of these contracts, specifically whether or not they should be recognized or enforced. Surrogacy is very controversial and is banned in many places. Surrogacy arrangements gone awry have led to highly publicized custody disputes in the United States, the United Kingdom and Australia.

Selective reduction, is also called selective feticide, selective embryocide or selective

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[8]See Law Reform Commission of Canada, *Medically Assisted Procreation, Working Paper 65* (Ottawa: Minister of Supply and Services Canada, 1992) at 31-32.

abortion. This procedure stops the development of a living foetus usually by injecting a lethal substance into its heart *in utero*.[9] To combat relatively low ART success rates, physicians frequently create and implant more than one embryo during a single cycle. These practices increase the chances of multiple births, gestational complications and fetal and maternal morbidity and mortality. Fertility drugs also carry an increased risk of multiple order pregnancy. If a multiple order pregnancy is detected, selective reduction is used to improve the fates of the remaining fetuses and the mother. The foetus stops developing but remains in *utero* and is eventually delivered along with the other foetuses. Selection is performed for a variety of reasons: genetic defect or disease, sex, size, apparent health or location. There are several risks involved with the procedure: spontaneous abortion of all embryos, infection or other complications for the mother and other embryos, and failure to cease development of the selected embryo. Selective reduction creates a painful ironic dilemma for people seeking a child of their own. The use of this procedure raises concerns about the dignity of human beings and the appropriate limits on other infertility treatments and the proper reasons for selective reduction.

B. Identifying the Interested Parties

The parties claiming an interest in regulating ARTs can be loosely divided into groups: parents, patients, donors, providers, progeny, legislators, the public and others. These groups are not mutually exclusive. ARTs involve four types of parents: genetic, gestational, legal and social/intended. Parents may also be donors or patients. Donors supply the raw reproductive

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[9]Selective reduction was offered at 5 of the 16 fertility clinics surveyed in *Proceed with Care, supra* note 1 at 525.

materials used in ARTs. They may or may not wish to have subsequent control or involvement once they have surrendered the physical custody of their gametes and embryos. Patients can be male or female, but women are subject to the more physically intrusive treatments. Women have traditionally been defined by their reproductive roles. Their status, rights and obligations are disproportionately affected by ARTs and the regulation of ARTs. The progenies of assisted reproduction (preembryos, embryos, foetuses and children) are also a key group. Many members of this group cannot represent their own interests. The oldest members of this group are only now young adults. Therefore, others frequently purport to speak for the progeny, but these others often support individual sacrifices to further the collective interests of the entire group that would be unacceptable with other groups of persons. Then there are providers: the medical profession, professional self-regulating bodies, and the owners and administrators of facilities and programs. Providers may operate in purely private markets, purely public markets or in combination markets. Regardless of the setting, all providers have professional obligations and personal interests and aspirations involved in these transactions. Providers invent the services. They control access and availability. They maintain custody or physical control of source materials before and after fertilization. This influential and dominant group has shaped the characterization of and approaches to regulation of ARTs in the past. The government is also involved in many capacities. It may be a direct or an indirect provider or payor. It is the legal entity charged with authority to control the provision of ARTs and to set and enforce normative standards and limits. It is also responsible for protecting both potential users and the public at large. The public at large and segments of it often assert an interest in these technologies for financial and ethical reasons. Finally, civil rights groups, women's groups, homosexual groups, disabled groups and other

groups have also asserted special interests in regulating treatment options. The existence of these groups coupled with the diversity amongst and within them makes consensus building and ART policy development difficult particularly in rights-based cultures like Canada.

C. Categorizing the Transaction - Medical Need or Social Desire

Assisted reproduction can be described as a medically required treatment, a technical means to fulfill an essentially social need, or a continuum of services classified in accordance with the reasons for seeking assistance or the cause of infertility.[10] Categorization is legally significant as it determines the placement of the subject matter within a given system of laws and governing principles. Categorization also has a strong symbolic impact and it may be a key factor in grounding assertions of entitlement. [11] Categorization may also be used to either avoid or justify substantive interference in the provision of ARTs. Categorization is practically

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[10]Under the continuum approach, blocked fallopian tubes constitute a medical condition warranting the allocation of public resources and treatment by medical professionals, whereas advanced age or sexual orientation constitute mere social factors which may not warrant the use of public resources. It is important to note also that the female "patient" may be perfectly fertile and undergoing procedures due to the infertility of her nonpatient spouse.

[11]According to the RCNRT categorization is key because it has implications for prevention and for whether ARTs should be provided through the publicly funded health care system, *Proceed with Care*, *supra* note 1 at 172. The RCNRT concluded that these services are really a combination. The Commission later uses this conclusion to justify recommendations for substantive regulation at 19-20:

> Assisted conception services, for example, and research, technologies, and medical interventions they involve, are not designed to cure illness or disease in a traditional pathological sense, but rather to address the problem of involuntary childlessness - a condition whose significance and implication for the individuals involved and for society as a whole, are of a predominantly social rather than medical character. Prenatal diagnosis services, research involving human zygotes and the use of fetal tissue, and prenatal genetics involving human zygotes and the use of fetal tissue, and prenatal genetics research also have distinct ethical and social significance owing to their unique relationship to human reproduction. More than any other aspect of health-related technology or service, the research and application of new reproductive technologies have significance beyond the individuals directly involved.
>
> Public control over the development and use of new reproductive technologies is therefore necessary to safeguard a wide range of interests. Some relate directly to the health and well-being of the individuals involved. Others relate to the welfare of particular groups such as woman... Still others relate to the well-being of Canadian society as a whole, including that of future generations , and have implications beyond Canadian borders.

important in Canada where free and universal health care predicated upon medical need as determined by a physician is considered an indispensable social entitlement. While full health care is a cornerstone of Canadian culture, other social programs are not seen in quite the same light. Further, other programs do not have the strong support of the medical profession as advocate, provider and gatekeeper.[12] Regardless of whether they have been classified as a social or a medical issue, ARTs have traditionally been accessed through medical intermediaries and are therefore subsumed within the areas of law which govern medical practice and patient/physician relationships. Classification as a medical procedure is therefore warranted regardless of the patients' motives solely because patient safety requires that the services be provided by properly trained professionals and professionals are inevitably involved with the newer and more technical procedures.

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[12]Categorization is also a concern in countries which do not provide public health insurance. These jurisdictions may still have laws mandating the provision of medical as opposed to social services. For instance the state of Texas has enacted specific provisions forcing employers to cover some, but not all ARTs within standard employee medical insurance plans if specified conditions are satisfied: *Vernon's Texas Statutes and Codes, Annotated Insurance Code*, c.3, subchapter E, Art. 3.51-6, s.3A. (West Group 1997).

CHAPTER THREE: *Health Care and ARTs in Canada*

Health care is a key political issue in Canada. There is a deep commitment to the provision of comprehensive services (free at the point of service) and a long tradition of deference to professional judgment and to the self-regulation policy model. Since physician involvement is almost inevitable, particularly for technologically intensive procedures, ARTs occur within this politically sensitive context. This chapter examines the many layers forming the Canadian legal landscape within which ARTs are provided. It reviews existing laws that incidentally apply to ARTs, providing background about the traditional legal regulation of the patient/physician relationship and the unique issues raised by the Canadian Constitution.[1] The evolution of law with respect to health care generally and ARTs in particular are also discussed.

A. General Principles Governing the Patient/Physician Relationship

This section outlines the main common law obligations governing patient/physician

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[1]In Canada, both the division of powers in s.91 and s.92 of the *Constitution (Constitution Act,* 1882, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c.11) and the *Charter of Rights and Freedoms* (Part I of the *Constitution Act, 1982,* being Schedule B to the *Canada Act 1982* (U.K.), 1982, c.11) limit the degree to which governments can implement legislation regulating ARTs.

Similar constraints apply in other federal nations such as the United States and Australia. In both of these countries a national consensus does not exist and conflicting laws have been enacted in various states. See chapter 6, *infra.* and see R. Blank & J. Merrick, *Human Reproduction, Emerging Technologies and Conflicting Rights* (Washington, D.C: Congressional Quarterly Press, 1995) at 21-22. Switzerland provides another example of constitutional limitations upon legislative action. In 1992 the Swiss constitution was amended to include specific principles to protect human dignity, personality and family. It prohibits interventions affecting genetic heritage of human gametes, mixture with nonhuman species, embryo donation and surrogacy, and commerce in embryos and germ-cell heritage. It restricts the use of ARTs and the creation of excess embryos. Further there are restrictions on the use of genetic heritage information and guarantees of access to information for ART offspring. A summary of the amendment is reproduced at (1992) 43 I.D.H. L. 745.

relationships.[2] Physicians are subject to legally enforceable obligations about standards of care, pretreatment disclosure and consent, and confidentiality. Recently the courts have emphasized that the physician, as a fiduciary, is subject to an overarching obligation to act in utmost good faith and to prevent personal interests from coming into conflict with professional obligations.[3] A breach of any of these obligations may be remedied by civil litigation and ultimately monetary compensation. Breaches may also be redressed through criminal prosecution, professional disciplinary proceedings or other remedial procedures.

When individuals seek procreative assistance, particularly technical procedures such as IVF, medical practitioners are invariably involved. This involvement triggers patient/physician relationships which carry specific legal implications. Patient/physician relationships are characterized by trust and power imbalances. Patients are subject to information deficits and must place faith and confidence in professionals who occupy powerful and influential positions due to specialized knowledge and a legal monopoly over the provision of specific services which are essential to the patient's well being. Further it is difficult, often impossible, for patients to independently assess the knowledge or skill of physicians. Over time the law has developed, and continues to develop, special rules to compensate for these inequities.

Patient/physician relationships and the legal categorization of these relationships have evolved from relationships arising from a professional calling, to paternalistic relationships, to

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[2]Some of these principles have been altered or enhanced by statute in certain jurisdictions, however, a comprehensive jurisdiction by jurisdiction review of these alterations is beyond the scope of this thesis.

[3] See e.g. *McInerney v. MacDonald* (1992), 93 D.L.R. (4th) 415 (S.C.C.) at 423.

partnerships in treatment.[4] Changes in the specific rules and responsibilities imposed under common law reflect these developments. Throughout this evolution there has been a perpetual tension for policy makers between the need for deference to professional decision making (collective and individual) and the need for externally imposed legal obligations and checks to ensure the well being of the patient, to account for professional self-interests and to compensate for the inequalities inherent in the relationship. This tension has been acute regarding ARTs.

1. Standards of Care

Physicians are not required to take on every potential patient, but once they agree to treat a particular patient, they are obliged to continue to provide treatment until that patient has been given a reasonable opportunity to find alternative care.[5] Once patient/physician relationships are established, physicians must exercise due care in making decisions regarding diagnosis, treatment, referral and disclosure. They must practice with the degree of care, skill and competence which it would be reasonable to expect of an average prudent practitioner in the same discipline in similar circumstances. Specialists are held to a higher standard of care - that of the average specialist in the same area of expertise.[6] In addition, physicians must adhere to established standards of practice within the medical field generally. Adherence is usually sufficient to exonerate them from civil liability. However, if the professional standards

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[4] E. Picard & G. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. (Scarborough: Carswell, 1996) at 1-5 [hereafter *Doctors and Hospitals in Canada*].

[5] In some jurisdictions there are statutory provisions allowing physicians to refuse to provide treatment based upon their individual beliefs and consciences.

[6] See *Lapointe v. Hospital le Gardeure*, [1992] 1 S.C.R. 351 at 361 -364 and *terNeuzen v. Korn*, [1995] 10 W.W.R. 1 at 14-15 (S.C.C.).

themselves prove inadequate, or fraught with obvious risks, then physicians are expected to exceed them in providing treatment.[7] If a physician fails to meet the expected standard of care and injures the patient, the patient may pursue legal recourse through a civil action for negligent malpractice.

2. Disclosure And Informed Consent

The common law recognizes that patient/physician relationships have changed to accommodate a higher level of patient participation. This increased involvement is reflected in the fact that respect for patient autonomy is now a central legal principle. To preserve autonomy and to compensate for the traditional knowledge imbalance inherent in the relationship, physicians are legally obliged to obtain informed consent or permission from patients prior to treating them. There are many prerequisites to legally informed consent. Consent must relate to the proposed treatment and must be given voluntarily by a competent adult. It is vitiated if obtained by fraud or misrepresentation. Physicians must advise patients about their conditions and the nature of any proposed treatment, as well as the risks associated with treatment including the nature and likelihood of those risks.[8] More specifically, the law obliges disclosure of all unusual risks and all risks that would be material to a reasonable patient in the patient's position. Physicians must also disclose the true chances of failure of the proposed treatment and the relative benefits and risks of alternative treatment

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[7] *ter Neuzen v. Korn, ibid* at 17 (S.C.C.).

[8] *Hopp v. Lepp*, [1980] 2 S.C.R. 192.

options.[9] In the case of experimental procedures, physicians must disclose additional information.[10] Physicians must always ensure that their patients have understood the disseminated information.[11] In very limited circumstances, physicians may withhold certain information if treatment is necessary to preserve the patient's life or health and nondisclosure is justifiable given the emotional state of the patient.[12]

In some situations legislation requires the use of prescribed consent forms as evidence of informed consent. Many physicians voluntarily employ consent forms to facilitate and provide evidence of disclosure and informed consent. Some provinces have codified the law regarding consent for all patients,[13] while others have supplemented the common law in situations where the patient cannot personally give informed consent.[14] While consent forms are useful, they do not absolve physicians from the obligation to fully disclose relevant information. If physicians fail to obtain informed consent they may be liable in battery or negligence

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[9]*Reible v. Hughes*, [1980] 2 S.C.R. 880. The Supreme Court of Canada adopted a patient-based, rather than a physician-based, standard of disclosure. Physicians are obliged to disclose what a similarly situated, reasonable patient would like to know rather than what a reasonable physician would be likely to disclose. This view was later affirmed in *Ciarlariello v. Schacter* (1993), 100 D.L.R. (4th) 609 at 617 (S.C.C.).

[10]*Halushka v. University of Saskatchewan* (1965), 52 W.W.R. 608 (Sask. C.A.). See also *Doctors and Hospitals in Canada*, *supra* note 4 at 149-151 outlining this and other key cases concerning the additional obligation to disclose the true opportunity costs of participation in research or experimental procedures. See also the discussion of the new federal *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*, below.

[11]*Reible v. Hughes*, *supra* note 9.

[12]*Hopp v Lepp*, *supra* note 8.

[13]See e.g. the *Health Care (Consent) and Care Facility (Admission) Act.*, R.S.B.C. 1996, c.181 and the *Health Care Consent Act*, S.O. 1996, c.2.

[14]See e.g. the *Dependent Adults Act*, R.S.A. 1980 c. D-32.

depending upon the circumstances.[15]

3. Confidentiality

Communications between patients and physicians are not legally privileged,[16] however, physicians are obliged to maintain confidentiality over information obtained from patients.[17] Physicians must not disclose information about patients unless required to do so by a court or by legislation. The common law obligation of confidentiality has been altered by many statutes which allow or dictate disclosure for reasons of public welfare, public safety and child welfare and also by information and privacy legislation.[18] Patients are entitled to access the information in their own files and to copy that information, unless the physician can establish that nondisclosure is warranted to prevent a real potential for harm to the patient or to another party.[19] If the physician fails to maintain information in confidence, then the patient can initiate an action for breach of confidence.[20]

B. Constitutional Jurisdiction Over Health Care in Canada

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[15]*Reible v. Hughes, supra* note 9 provides that if consent is obtained based upon incomplete or erroneous information then the patient may sue in negligence not battery. This places a more onerous evidentiary burden on the plaintiff. See also *Ciarariello v. Schacter, supra* note 9 at 616-617.

[16]*Halls v. Mitchell* (1928), S.C.R. 125.

[17]*McInerney v. MacDonald, supra* note 3.

[18]E. Oscapella, "Overview of Canadian Laws Relating to Privacy and Confidentiality in the Medical Context", *Overview of Legal Issues in New Reproductive Technologies, Research Studies of the Royal Commission on New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply and Services Canada, 1993) 171.

[19]*McInerney v. MacDonald, supra* note 3.

[20]*Doctors and Hospitals in Canada, supra* note 4 at 35-37.

All statutory regulation of health care and ARTs must be achieved within the existing Constitutional division of powers. Historically, the responsibility over health care and social programs was left to the most local levels of government. At the time the Constitution was drafted, it was not anticipated that a national universal health care system would become an integral part of Canada, nor that health services would become a huge industry heavily regulated by both levels of government. It is therefore not surprising that the Constitution does not explicitly allocate the areas of health care, social welfare or ARTs to either the provinces or Parliament. While the proper situs of legislative authority over the area is not entirely certain, health care has been treated as a predominantly provincial responsibility. However, the courts have also recognized a legitimate latitude for federal legislation in certain health care areas.[21]

In 1982, the Supreme Court of Canada addressed the constitutional validity of a provincial act prescribing mandatory treatment for heroin addicts. In *R. v. Schneider,*[22] Mr. Justice Dickson delivered the majority judgement (unanimous in result) upholding the law because, in pith and substance, it dealt with the treatment of illness, a provincial matter. He rejected the argument that the law encroached upon the federal jurisdiction over criminal matters. He emphasized the dominant role of the provinces in matters pertaining to health care.[23]

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[21]Canadian Bar Association Task Force on Health Care, *"What's Law Got to Do With It?" Health Care Reform in Canada* (Ottawa: The Association, 1994) at 15-19 [hereafter *What's Law Got to Do With It?*]. See also the majority decision in *R.J.R. Macdonald Inc v. Canada,* [1995] 3 S.C.R. 199.

[22]*R. v. Schneider* (1982), 139 D.L.R. (3d) 417 (S.C.C.).

[23]In reaching this conclusion, in *Schneider, ibid* at 438-439, Justice Dickson quotes two portions of the 1938 Royal Commission on Dominion- Provincial Relations (The Rowell-Sirois Commission):

> In 1867 the administration of public health was still in a very primitive stage, the assumption being that

According to Justice Dickson, "that the general jurisdiction over health matters is provincial (allowing for a limited federal jurisdiction either ancillary to the express heads of power in s.91 or the emergency power under peace, order and good government) has prevailed and is now not seriously questioned."[24] In a separate judgement, Mr. Justice Estey elaborated further on the dual nature of health care providing an excerpt frequently quoted[25] to support federal health-related legislation: [26]

> Health is not a subject specifically dealt with in the *Constitution Act* either in 1867 or by way of subsequent amendment. It is by the constitution not assigned either to the federal or provincial legislative authority. Legislation dealing with health matters has been found within the provincial power where the approach in the legislation is to an aspect of health, local in nature....On the other hand, federal legislation in relation to "health" can be supported where the dimension of the problem is national rather than local in nature...or where the health concern arises in the context of a public wrong and the response is a criminal prohibition...Health concerns are directly raised by the jurisdiction attributed to Parliament by s.

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health was a private matter and state assistance to protect or improve the health of the citizen was highly exceptional and tolerable only in emergencies such as epidemics, or for purposes of ensuring elementary sanitation in urban communities. Such public health activities as the state did undertake were almost wholly a function of local and municipal governments. It is not strange, therefore, that the British North America Act does not expressly allocate jurisdiction in public health, except that marine hospitals and quarantine (presumably ship quarantine) were assigned to the Dominion, while the province was given jurisdiction over other hospitals, asylums, charities and eleemosynary institutions. But the province was assigned jurisdiction over "generally all matters of a merely local or private nature in the Province," and it is probably that this power was deemed to cover health matters, while the power over "municipal institutions" provided a convenient means for dealing with such matters.

The Rowell-Sirois Commission recommended that (at p.34):

> Provincial responsibilities in health matters should be considered basic and residual. Dominion activities on the other hand, should be considered exceptions to the general rule of provincial responsibility, and should be justified in each case on the merit of their performance by the Dominion rather than by the province ... Dominion jurisdiction over health matters is largely, if not wholly, ancillary to express jurisdiction over other subjects...

[24]*Schneider, supra* note 22 at 439. *Schneider* is cited on this point by Mr. Justice LaForest speaking for the court in *Eldridge v. British Columbia (A.G.),* [1998] 1 W.W.R. 50 (S.C.C.) at 68.

[25]See e.g. M. McTeer, *Technology in the Field of Human Reproduction: A Medical/Scientific Challenge to Canadian Law,* (LL.M. Thesis, Dalhousie University, 1993) at 117-118; D. Gibson, "The *Canada Health Act* And the Constitution" (1996) 4 Health L. J. 1 at 1-2; and, *What's Law got to Do With It?, supra* note 21.

[26]*R. v. Schneider, supra* note 22 at 442-443.[Citations omitted.]

> 91(11) of the *Constitution Act, 1867*, and may also be raised by s. 91(7) and perhaps para. (2) as well. In sum "health" is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending on the circumstances of each case or the nature or the scope of health problem in question.

The general provincial legislative jurisdiction over health and ARTs arises pursuant to several matters listed in s. 92 of the Constitution including authority over: hospitals, asylums, charities and eleemosynary institutions, other than marine hospitals; property and civil rights in the province; and, matters of a merely local or private nature in the province. Courts have explicitly confirmed provincial authority to regulate many professions,[27] including the medical profession,[28] as part of the legislative jurisdiction over property and civil rights. The authority to regulate professions includes legislative authority over the standards of qualification, prohibitions barring others from practicing and the creation of administrative agencies to establish and enforce standards of practice and ethics.[29] However, provincial authority over health care services is not absolute. In the area of human reproduction, certain statutes dealing with abortion have been struck down as colourable attempts to legislate morality and usurp federal authority over criminal law.[30]

The federal legislative authority with respect to particular aspects of health care arises

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[27]E.g. the legal profession: *Canada (A.G.) et al. v. Law Society of B.C.*, [1982] 5 W.W.R. 289 (S.C.C.).

[28]*Lafferty v. Lincoln* (1907), 37 S.C.R. 620.

[29] The courts have upheld provincial laws making breaches of professional standards offences. See J. Casey, *The Regulation of Professions in Canada*, looseleaf (Scarborough: Carswell, 1994 at 2-1 - 2-3.

[30]See e.g.: *R. v. Morgentaler (No. 3)*, [1993] 3 S.C.R. 463; *Re Freedom of Informed Choice (Abortions) Act* (1985), 25 D.L.R. (4th) 751 (Sask. C.A.). See also M. L. McConnell, "Abortion- Provincial Legislation- Control Over Health Care: *R. v. Morgentaler*" (1994) 73 Can. Bar Rev. 417.

pursuant to s. 91 authority over: trade and commerce,[31] militia, military, naval service and defence; quarantine and marine hospitals; Indians and lands reserved for Indians; and, naturalization and aliens. Parliament may also claim broader authority over health and ARTs under the federal spending powers, criminal powers,[32] or residuary powers to make law for the peace, order and good government of Canada ("POGG"). In practice, the constitutional division of powers "has not prevented the federal Parliament from playing a leading role in the provision of free, universal medical care throughout the nation. It has done so by employing its inherent spending power to set national standards for provincial Medicare programs."[33] Parliament has exercised considerable steering influence and control through the provision of conditional financing for matters within provincial authority.[34] Following the precedent of many other compartmentalized social grant programs, the federal government could employ the spending power to enact a positive regulatory scheme or a system of national standards within a conditional grant system specific to ARTs. The two remaining sources of constitutional power to enact national laws directly regulating health care services and patient/physician relationships in the ART context are the federal authority over criminal law and the residuary POGG power. While the full extent of these powers is uncertain, both were recently considered by the Supreme Court of Canada.

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[31]While the trade and commerce power could also be used to regulate certain aspects of NRTs, this head of legislative authority has been narrowly interpreted by the courts. See P. Hogg, *Constitutional Law of Canada*, looseleaf (Scarborough: Carswell, 1997) at 20-1 - 20-16.

[32] Health is a legitimate public concern basis upon which criminal laws may be founded, *Reference re Validity of S. 5(a) of Dairy Industry Act (The Margarine Reference)*, [1949] S.C.R. 1; Aff'd [1951] A.C. 179 (P.C.). an Hogg, *supra* note 31 at 18-11 - 18-12.

[33] Per LaForest in *Eldridge v. B.C. (A.G.)*, [1988] 1 W.W.R. 50 (S.C.C.) at 68.

[34]For a detailed discussion of the spending authority and of the constitutional authority for the *Canada Health Act* R.S.C. 1985, c. C-6, see D. Gibson, "The *Canada Health Act* and the Constitution," *supra* note 25 at 5-16.

The criminal legislative authority is described as broad and evolving, but not boundless. Criminal laws must involve prohibitions and penalties that relate to some underlying legitimate public purpose. This head of legislative authority could not support a full regulatory scheme which would alter the constitutional division of powers or otherwise constitute a colourable intrusion on provincial authority. The line between criminal prohibition and substantive regulation is not clear. A majority of the Supreme Court of Canada has been quite generous in its assessment of the quantum of regulation required to strip an enactment of its criminal character. Recently, the Court upheld very detailed laws which appeared regulatory rather than penal in nature. In 1995, in *R.J.R. MacDonald v. Canada (A.G.)*[35] the Supreme Court of Canada upheld a federal law regulating tobacco advertising and requiring mandatory health warnings on tobacco products under the criminal law legislative jurisdiction.[36] The majority first noted that the protection of the public from the undeniable harmful effects of tobacco use was a valid public purpose. Then, given that an outright prohibition of tobacco would not be feasible in Canada, they endorsed the use of innovative legislation restricting advertising as part of a long term comprehensive health-oriented policy.[37] Further, the majority acknowledged that valid criminal laws can be regulatory in the sense that they may create exemptions to prohibited conduct in order to define crimes and clarify the contours of

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[35] [1995] 3 S.C.R. 199 [hereafter *R.J.R. MacDonald*].

[36] Ultimately the Court struck these health related laws for violating the free speech rights set out in the *Charter*.

[37] *R.J.R. MacDonald, supra* note 35 at 252

> This Court has long recognized that Parliament may validly employ the criminal law power to prohibit or control the manufacture, sale and distribution of products that present a danger to public health, and that Parliament may also validly impose labelling and packaging requirements on dangerous products with a view to protecting public health.

acceptable conduct.[38] Mr. Justice Major dissented, ruling that while exemptions do not necessarily strip a statute of its criminal character, broadly based exemptions are a factor which may lead a court to conclude that the proscribed conduct is not truly criminal. He would have invalidated the law because it failed to address a serious social wrong.[39]

In 1997 in *R. v. Hydro-Quebec,*[40] a majority of the Supreme Court of Canada again adopted a generous view of the criminal law power. The Court upheld a very detailed scheme to protect the environment by controlling and preventing the release of toxic substances. While all the justices agreed that protection of the environment (like health) was a proper matter for public protection and criminal legislation, they disagreed on the nature of the statute at issue. Mr. Justice La Forest for the majority described the limits of the criminal law power:[41]

> The national concern doctrine operates by assigning full power to regulate an area to Parliament. *Criminal law does not work that way. Rather it seeks by discrete prohibitions to prevent evils falling within a broad purpose, such as, for example, the protection of health.* In the criminal law area, reference to such broad policy objectives is simply a means of ensuring that the prohibition is legitimately aimed at some public evil Parliament wishes to suppress and so is not a colourable attempt to deal with a matter falling exclusively within an area of provincial legislative jurisdiction.

He held that the environmental law was sufficiently narrow to qualify as a criminal statute because the regulations simply defined toxic substances and then prohibited only those

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[38]*R.J.R. MacDonald, supra* note 35 at 266 citing Stevenson J. in *R. v. Furtney,* [1991] 3 S.C.R. 89 at 106-107.

[39]*R.J.R. Mac Donald, supra* note 35 at 363. Justice Major (with the support of Sopinka J.) would have restricted criminal law to the prohibition of conduct which interferes with the proper functioning of society, undermines the safety and security of society as a whole, or poses a significant and serious risk of harm, at 359 "lesser threats to society and its functioning do not fall within criminal law but, are addressed by non-criminal regulation either by Parliament or provincial legislature, depending on the subject matter of the regulation."

[40]*R. c. Hydro Quebec,* [1997] 3 S.C.R. 213.

[41]*R. c. Hydro Quebec, supra* note 40 at 297.[Emphasis added.]

substances falling within the definition. He noted that this exercise of federal criminal law power had not prevented the provinces from extensively regulating in the area and that the law did not distort the federal-provincial balance of legislative authority.[42] In contrast, the minority held that while the impugned act possessed a legitimate criminal purpose, it was regulatory not prohibitory in nature.[43] They found the act to be extremely broad, pointing to administrative discretion inherent in the scheme and to the many provisions that regulated the ways in which substances come into contact with the environment rather than prohibiting discrete acts. The minority found these characteristics to be substantial indicia of regulation rather than criminal prohibition.

These cases confirm that the federal criminal law power is not restricted to statutes which merely recite criminal acts and respective penalties. The Supreme Court of Canada currently appears prepared to accept rather broad and detailed federal laws enacted to protect public interests in areas such as health. However, it seems unlikely that the criminal law power could be cited as authority for the creation of a comprehensive national regulatory system governing the provision of ARTs such as the one proposed by the Royal Commission on New Reproductive Technology.[44] "In other words, while the federal government cannot rely on the criminal law power to support complex regulatory intervention in relation to NRTs, the

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[42]*R. c. Hydro Quebec, supra* note 40 at 295. Interestingly he uses health as an example of an area where federal criminal prohibitions have not foreclosed extensive provincial regulation. In the writer's view, comprehensive NRT legislation would do exactly what LaForest says should not be done.

[43]Per the dissent of Lamer C.J. (Sopinka, Iacobucci and Major JJ) in *R c. Hydro Quebec, supra* note 40 at 244.

[44]See *Proceed with Care Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Supply and Services Canada, 1993) at 107-128. The Commission is hereafter the RCNRT, the report is *Proceed with Care*.

criminal law power will support an array of prohibitions and sanctions in this area."[45] The mere use of criminal sanctions cannot change the regulatory pith and substance of an enactment which is really designed to control an industry and the activities of individuals within the provinces.[46]

The final possible source of federal authority to directly and comprehensively regulate health and NRTs is the national concern branch of the residuary POGG power.[47] POGG has been used to support federal laws about temperance, aeronautics, planning within the national capital region, marine pollution, and atomic energy. To fall within the national concern aspect of POGG, legislation must pass two tests: the distinct subject matter test and the provincial inability test.[48] First, the legislation must relate to a subject matter which possesses a singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern and it must also have a scale of impact on provincial jurisdiction that is reconcilable with the Constitutional distribution of legislative powers. The distinct matter may

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[45]M. Jackman, "The Constitution and the Regulation of New Reproductive Technologies" *Overview of Legal Issues in New Reproductive Technologies, Research Studies of the Royal Commission on New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply and Services Canada, 1993) 1 at 11.

The Canadian Bar Association reached a similar conclusion (*What's Law Got to Do with It?, supra* note 21 at 15):

> While criminal law is indisputably a matter within federal competence, it is a very blunt and heavy instrument, designed to restrain only the most unacceptable behaviour in society. Maintaining a basic standard of health care does not fit comfortably into such a regime. While the criminal law power may be a useful regulatory tool, it cannot be used to govern access to and delivery of health services.

[46]See *R.J.R. Macdonald, supra* note 35 at 246-247.

[47]The residual POGG authority applies only to areas not otherwise assigned to the provinces. It is divided into three types: the gap branch, the emergency branch and the national concern branch. The last branch empowers the federal government to legislate on matters that go beyond provincial concern and are inherently national concerns and is most relevant with respect to health and NRTs. For a brief review of cases on this aspect of POGG see Hogg, *supra* note 31 at 17-7 - 17-18.

[48]The test was established in *R. v. Crown Zellerbach,* [1988] 1 S.C.R. 401.

be either a new matter, or a matter which was originally of a local or private matter but has since become a national concern. Second, the distinct matter must be one which the provinces are unable to properly control in the sense that the failure of one province to agree to a nation-wide scheme will injure extra-provincial interests.[49] Courts have restrictively interpreted the POGG national concern power to preserve the constitutional division of legislative authority between the two levels of government.[50] POGG authority cannot be used to justify federal laws on that basis that uniform laws are laudable or desirable as the Canadian Constitution entrenches a federal system, not a unitary system. As Professor Hogg explains:[51]

> Uniformity is desirable with respect to many topics, and for many reasons, but of course the distribution of legislative powers in a federal system necessarily involves a substantial subordination of the value of uniformity to that of provincial autonomy even where there is no objective necessity for regional variations. In legislative fields which are entrusted to the provinces, it is for the provinces to decide whether or not they desire uniformity: they can achieve it whenever they wish through the enactment of uniform laws. If as is common, some provinces do not enact the uniform statute, or enact it with variations, no great harm is done, a substantial degree of uniformity will still have been achieved and will still be valuable. Even in fields entrusted to the federal Parliament, which uniform laws are usual, federal laws occasionally impose different rules on different parts of the country. There is no constitutional requirement of uniformity.
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> There are, however, cases where uniformity of law throughout the country is not merely desirable, but essential, in the sense that the problem " is beyond the power of the provinces to deal with it". This is the case when the failure of one province to act would injure the residents of the other (cooperating) provinces. This "provincial inability " test goes a long way toward explaining the cases. The often cited case of an epidemic of pestilence is a good example.

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[49]*R. v Crown Zellerbach, ibid.* at 431-432.

[50]In *R. c. Hydro-Quebec, supra* note 40, the minority found that the federal environmental legislation could not be supported under POGG. The Majority did not address the point having found the act to be a valid exercise of the federal criminal law power.

[51]Hogg, *supra* note 31 at 17-2 - 17-3.

While there may be some latitude for federal legislation under the spending and criminal law powers, comprehensive ART regulation under the POGG national concern doctrine seems unlikely to be upheld despite mixed academic views.[52] It is doubtful that ART specific laws would pass either national concern test. ARTs do not constitute a truly distinct area of law.[53] These issues are also very controversial. There is no consensus about the need for reform nor the effect of maintaining the status quo. There is no evidence that provinces are unwilling or unable to deal with the area or that substantive regulation specific to ARTs is preferable to the existing legal mechanisms governing the provision of medical services generally. There is no evidence that a failure to act will create extra-provincial harms. In the absence of such evidence, it would be difficult to assert that the provincial inability prerequisite to the exercise of the POGG authority has been satisfied. Further federal legislation, no matter how laudable, would represent a significant intrusion into provincial autonomy and existing legislative approaches to professional regulation, health care and patient/physician relationships. The mere fact that Parliament endorses a comprehensive national policy on ARTs is insufficient to bring the subject area within the legal definition of national concern.[54] Regardless of the

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[52]See Jackman, *supra* note 45 at 4-6.This is carried into the final report of the RCNRT in a brief passage that justifies federal regulation under the heads discussed, particularly the residual POGG power over matters of national concern as well and the trade and commerce powers and other unspecified powers due to the" overarching nature, profound importance and fundamental interrelatedness" of the issues involved in NRTs *Proceed with Care*, *supra* note 44 at 14-22. In P. Healy, "Statutory Prohibitions and the Regulation of New Reproductive Technologies under Federal Law in Canada" (1995) 40 McGill L.J. 905 at 916-919 the author notes that the RCNRT did not provide legal authority for its conclusions and criticises them. The Law Reform Commission of Canada also asserts federal jurisdiction without extensive comment under several heads of power including spending power, criminal power, residuary POGG power, trade and commerce power and human rights obligations *Medically Assisted Procreation- Working Paper 65* (Ottawa: Minister of Supply and Services Canada, 1992) at 115-119.

[53]Although the RCNRT asserts that it is self-evident that NRTs are a distinct and unique subject area, this seems doubtful. The limits of ARTs are not certain, they may include a vast number of medical and other procedures including genetic testing and other areas of human reproduction traditionally regulated by the provinces such as abortion and sterilization.

[54]Healy, *supra* note 52 at 918.

value of national standards, Canada's federal system of government must be respected.[55]

C. The Charter *and the Regulation of Health Care and ARTs*

In Canada and other western nations, conceptions of individual rights often frame legal discussions and developments. Although legal entitlements or rights are cornerstones of western democracies, they do not fit easily into the area of human reproduction which necessarily involves familial relationships as opposed to autonomous spheres of individual conduct.[56] Despite this difficulty, over time various individuals and groups have laid claim to (or denied the existence of) a set of reproductive rights covering the full process of human reproduction - from intercourse to conception and birth. These rights exist along a continuum encompassing positive, negative and mixed entitlements.[57] The continuum includes the right to control conception (this includes the right to access reliable means of contraception and sterilization); the right of access to abortion; the right to procreate; and most recently, the right to procreate "normal" or even "designer" children.[58]

This part focuses upon the latter end of this spectrum of reproductive rights - the right to procreate, more particularly the right to assisted procreation. To examine the impact of the

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[55]Even the federal research initiatives have conceded provincial authority over many of the key issues including the key derivative issues of child status and parental responsibility. See chapter 4 below..

[56]In the words of R. L. Stenger, "The Law and Assisted Reproduction in the United Kingdom and the United States" (1994-5) J. of L. & Health 135 at 138:"Family relationships, however, do not lend themselves to resolution in terms of dichotomous assertions of rights: Parent-child, mother- fetus, mother-father-child."

[57]See L. Shanner, "The Right to Procreate: When Rights Claims Have Gone Wrong" (1995) 40 McGill L.J. 823.

[58]See M. Moysa, "Baby Surfing" *the Edmonton Journal* (June 22, 1997) F1; J. Langton, "American Doctors Selling Made-to-Order Embryos," *the Daily Telegraph* reprinted in *the Edmonton Journal* (December 1, 1997).

Canadian Charter of Rights and Freedoms,[59] it is useful to separate two issues: the existence of a positive entitlement to procreative assistance (**availability** of services) and the limits or statutory controls which may be placed upon established programs (**accessibility** of available services). First, is the government obliged to make assisted reproductive services available at all? Second, if the government chooses to enact ART specific laws or implement ART programs, do those decisions create a secondary obligation to provide any and all services?

While the answers to these questions are not specified in the *Charter*, three sections are very germane: the s.7 rights to life, liberty and security of the person; the s. 15 equality rights; and, the s.1 limit on constitutional rights. Under s.7, the government may not interfere with rights to life, liberty or security of the person in a manner that either procedurally or substantively violates the principles of natural justice.[60] The full extent of each of these three rights is not clear, nor is the precise content of the principles of natural justice. Health care and perhaps procreative freedom may be a part of security of the person or possibly, part of the right to liberty. Section 15 entrenches four equality rights: equality before the law, equality under the law, equal protection of the law and equal benefit of the law. This section prohibits discrimination on the basis of the enumerated grounds (race, national or ethnic origin, colour, religion, sex, age or mental disability and physical disability) as well as any analogous

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[59]Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U. K.), 1982, c.11. s. 32.

[60]While fundamental justice includes substantive and procedural elements, the meaning of these elements are not entirely clear and are context dependent: *B.C. Motor Vehicle Reference*, [1985] 2 S.C.R. 486. In *R. v Morgentaler (No. 2)*, [1988] 1 S.C.R. 30 two judges found the restrictions upon access to abortion to be procedural restrictions while one found them to be substantive.

grounds.[61] The categories of analogous grounds are not closed and according to judicial precedent include marital status[62] and sexual orientation.[63] Section 1 limits the other constitutional rights. It provides that constitutional rights may be restricted or infringed if the limitation or restriction is prescribed by law and is reasonable in a free and democratic society. To validly curtail constitutional rights, the objective of the law must be a pressing and substantial concern. In addition, the restriction chosen to meet the objective must be rationally connected to the aim of the law, it must minimally impair the constitutional right and it must be proportionate to the legislative goal.

1. Availability: A Positive Entitlement to Assisted Reproduction

In assessing the possible existence of a positive right to assisted reproduction services, it is useful to segregate an independent entitlement to **procreative freedom**, from a general entitlement to **health services**. Either of these entitlements may encompass the right to ARTs.

a. The Independent Right to Procreative Freedom and Assisted Reproduction

Some authors suggest that there may be a free standing right of procreative freedom or right to parenthood based upon the *Charter*, more specifically that the s. 7 rights to life, liberty and security of the person may include a right of access to procreative services. There are no reported Canadian cases directly on point; however, the courts have been clear that the full

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[61] *Andrews v. Law Society of B.C.*, [1989] 1 S.C.R. 143.

[62] *Miron v. Trudel* (1995), 124 D.L.R. (4th) 693 (S.C.C.).

[63] *Egan v. Canada* (1995), 124 D.L.R. (4th) 609 (S.C.C.).

extent of life, liberty and security of the person are not yet known.[64] Certain comments of Mr. Justice LaForest in *E.(Mrs.) v. Eve* [65] as well as comments of Madame Justice Wilson in *Morgentaler (No. 2)*[66] are often cited to support the existence of such a right.

In *Re Eve* Mr. Justice La Forest refused to authorize the nontherapeutic sterilization of a mentally incompetent woman under the inherent *parens patriae* jurisdiction of the court. He held that the right to procreate was fundamental and that forced, nontherapeutic sterilization was a serious intrusion into basic individual rights. However, the judgment is limited as Justice LaForest found that the *Charter* was not applicable because the law was not being used to deprive any alleged s.7 rights, and he specifically refrained from any pronouncements about the full extent of s.7.[67] In *Morgentaler (No.2)*, Justice Wilson, dealing with the constitutional right of access to abortion, stated "the right to liberty contained in s.7 guarantees to every individual a degree of personal autonomy over important decisions intimately affecting their private lives."[68] While this definition of liberty seems broad enough to encompass the right to access ARTs, s.7 may never include such an entitlement for several reasons. Justice Wilson was the only judge to define liberty so broadly and she has since retired. Second, *Morgentaler No.2* deals with a criminal law restricting access to abortion, even in situations involving a proven danger to maternal health. This type of criminal

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[64]See *Medically Assisted Procreation, supra* note 52 at 77-84.

[65][1986] 2 S.C.R. 388.

[66]*Morgentaler (No. 2)*, [1988] 1 S.C.R. 30.

[67]*Re Eve, supra* note 65 at 436-438.

[68]*Morgentaler (No. 2), supra* note 66 at 171.

prohibition is clearly distinguishable from a freestanding positive entitlement to access the means of artificial procreation. Further, the rights in *Morgentaler No.2* encompassed both positive and negative elements, whereas a claim of free access to any means of assisted reproduction is a purely positive claim.

The above comments are simply inadequate to support a positive entitlement to access ARTs under s.7 of the *Charter*. Judge Rivet, writing for the Canadian Institute for the Administration of Justice, more accurately describes Canadian law: "[t]hese conceptions of liberty and security of the person could support a claim to noninterference with the right to procreate. However, they would not support a right to state-funded medically assisted reproduction."[69] Similarly, the Ontario Law Reform Commission uses impecuniosity as an example of the limits on positive obligations and argues that even if the government were required not to "impede the enjoyment of the right to procreate, it need not facilitate access to the means to procreate."[70]

In conclusion, there is very little legal foundation to compel Canadian governments to provide reproductive services or to enact a policy creating access to fully subsidized NRTs either within, or independent of, Canada's public health care system. Following Mr. Justice LaForest

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[69] M. Rivet, "Allocation and Rationing of Health Care Resources: Patients' Challenges to Decision-Making"in B. Dickens & M. Oulette, eds., *Health Care, Ethics & Law* (Ottawa: Les Editions Themis, 1993) at 32.

[70] Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters*, (Toronto: Ministry of the Attorney General, 1985) at 45. Even in the United States where a much larger range of procreative freedoms have been recognized, the courts have upheld the failure to cover the costs of abortion and assisted conception. For discussion of the American jurisprudence see Blank & Merrick, *supra* note 1 at 104-107 which suggests that the right to access services is uncertain and that there are mixed cases concerning the propriety of failing to provide services in public benefit packages. See also P. Neumann, "Should Health Insurance Cover IVF? Issues and Options" (1997) 22 J. of Health Politics, Policy & L. 1215.

in *Re Eve*, this type of nonfeasance would be a situation in which the *Charter* would not apply. Recently, in *Kings College v. Vriend*[71] the Supreme Court of Canada noted that positive acts as well as omissions will be subject to *Charter* scrutiny as silence is not necessarily neutral. However, *Vriend* involved the interpretation of under-inclusive legislation which conferred benefits in a discriminatory manner.[72] In Canada it appears that some form of government action would likely be required to trigger the potential for an independent obligation to provide procreative services.[73] In any event, such a right could be validly limited so long as the limitation occurs in accordance with the principles of fundamental justice. Finally, if a right of availability exists, it would not necessarily encompass an unlimited positive entitlement to all forms of procreative assistance for all patients.[74]

b. The Right to Assisted Reproduction as Part of the Right to Health Care

A legal right to ARTs could be encompassed within the larger generic entitlement to medical services. As governments gradually assumed primary responsibility for the provision of medically necessary health services, Canadians have come to expect universal health care, free at the point of service. Some authors have argued that the provision of essential health services is inherent in the rights to life, liberty and security of the person,[75] others deny the

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[71](1998), 156 D.L.R. (4th) 385 (S.C.C.).

[72]*Ibid.* at 411-412.

[73]See G. Shea, "Is There a Charter Right to Health Care in Canada?" *CBA Background Papers Submitted to the Canadian Bar Association, Whats' Law Got to Do with It?, supra* note 21 at 10-11.

[74]Shanner, *supra* note 57 at 832-834.

[75]See M. Jackman, "The Regulation of Private Health Care Under the *Canada Health Act* and the *Canadian Charter*," (1995) 6 Constit. Forum 54 at 56. She supports this conclusion in part upon *obiter* comments of Madam Justice Wilson in *Stoffman v. Vancouver General Hospital*, [1990] 3 S.C.R. 483 at 544 a case dealing with the

existence of any such right.[76] However, there is no express constitutional right to health services, nor to procreation *per se*.[77] The courts have not confirmed a positive entitlement to health care, nor to other social services. They have confirmed that s.7 does not protect property rights, nor purely economic interests which may mean that there is no positive right to access free health care services.[78]

Few reported cases consider a constitutional obligation to provide specific medical services within the existing public system. Generally, the courts have been quite reluctant to place specific positive obligations upon democratically elected authorities or their delegates who must allocate limited health resources and make hard choices.[79] For example, in *Brown v.*

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applicability of the *Charter* to a hospital's mandatory retirement policy. She also asserts an argument can be made for a positive right to participate in health allocation decisions at the policy level in M. Jackman, "The Right to Participate in Health Care and Health Resource Allocation Decisions Under Section 7 of the *Canadian Charter*," (1995) 4:2 Health L. Rev. 3.

[76]See *What's Law Got to Do With It?, supra* note 21 and also B. Windwick, "Health Care and Section 7 of the *Canadian Charter of Rights and Freedoms*" (1991) 3:1 Constit. Forum 20 at 22 who concludes that provision of services is unlikely to be guaranteed by s. 7 because health is considered to be an enhancement of the rights guaranteed in s.7. He concludes s.7 is more likely to be attracted to laws creating active barriers to access.

[77] Section 36 of the *Charter* states that both levels of government are committed to:

a) promoting equal opportunities for the well-being of Canadians;
b) furthering economic development to reduce disparity in opportunities; and ,
c) providing essential public services of reasonable quality to all Canadians.

Parliament also stated its commitment to providing provinces with sufficient revenues to ensure reasonably comparable levels of public services for reasonably comparable taxation levels. During the Charlottetown Accord negotiations, an explicit right to health care was proposed, but not ultimately included in the final draft. Section 36.1 (2) of the draft "included the following as one of the policy objectives of the social union: A) providing throughout Canada a health care system that is comprehensive, universal, portable, publicly administered and accessible": *What's Law Got to do With It?, supra* note 21 at 24-25.

[78]See Hogg, *supra* note 31 at 44-12-44-13.

[79]See Jackman, *supra* note 45 at 28 citing the Supreme Court of Canada in *McKinney v. University of Guelph*, [1990] 3 S.C.R. 229 on this point.

B.C.(Minister of Health)[80] the B.C. Supreme Court upheld a ministerial order removing the drug AZT from the list of insured drugs. The Court emphasized the difficult policy decisions involved in the allocation of limited resources and the unavoidable dilemma created by burdensome positive obligations, noting "[t]here is force in the argument... that a government, unable to confer benefits on any person unless it confers an identical benefit on all, will be faced with one viable option: of conferring benefits on no one."[81]

The Ontario General Division Court showed similar restraint in *Wellesley Central Hospital v. Ontario (Health Services Restructuring Commission).*[82] The hospital and individual applicants sought to quash the directions of the Health Services Restructuring Commission (the "Commission.") Under the restructuring plan, Wellesley Public Hospital was closed and its services redeployed to a Catholic institution. The individual applicants claimed their rights guaranteed by ss. 2(a), 7 and 15(1) of the *Charter* were infringed by this decision.[83] Some argued the religious nature of the hospital would create a discriminatory environment for homosexuals seeking HIV/AIDs treatments. Others argued that women's rights were infringed as the Catholic health care mission of the hospital condemned certain services, including abortion, sterilization as a form of birth control, birth control counselling and AI and IVF between unmarried persons. At the outset, the Court noted that its role was very

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[80](1990), 66 D.L.R. (4th) 444 (B.C.S.C.) [hereafter *Brown*]. For other examples in the administrative law context see K. Cherniawsky, "Enforcement of Health Care Rights and Administrative Law" (1996) 4 Health L. J. 35.

[81]*Brown, ibid.* at 463.

[82](1997), 3 Admin. L.R. (3d) 137 (Ont.C.J.(Gen. Div. Div Court)) [hereafter *Wellesley*].

[83]Wellesely Hospital also challenged the decision on several purely administrative law grounds, see *infra*.

limited.[84] The Court rejected the arguments on several basis. First, there was an absence of evidence that the applicants or any other patients would be forced to receive treatment at the Catholic hospital because comparable services were available elsewhere within the general catchment area. The Court also found that the religious aspect of the hospital did not violate the potential patients' rights and could not do so if it were possible for them to obtain services elsewhere. Finally, the Court ruled that the alleged breaches were prospective, and that the applicants had failed to prove it was highly probable that the alleged effects would materialize.

However, this issue is not dead. The Supreme Court of Canada recently adopted a more interventionist approach, indicating that the *Charter* may be used to impose certain positive obligations integral to making an equal bundle of services universally available within the public health care system. Mr. Justice LaForest for the unanimous Court in *Eldridge v. B.C.*[85] ruled that the *Charter* dictates that all patient groups must receive access to a comparable set of public services. Further, hospitals are subject to s.15 in allocating health resources. Accordingly, he concluded that hospitals must provide communication services for the deaf in furnishing the bundle of medical services available to all members of the public. However,

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[84]*Wellesley, supra* note 82 at 141 quoted Justice Campbell in *Pembroke Civic Hospital v. Ontario (Health Services Restructuring Commission)* (1997), 36 O.R. (3d) 41 (Ont. Div. Ct.):

> The courts' role is very limited in these cases. The court has no power to inquire into the rights and wrongs of hospital restructuring laws or policies, the wisdom or folly of decisions to close particular hospitals, or decisions to direct particular hospital governance structures. It is not for the court to agree or disagree with the decision of the Commission. The law provides no right of appeal from the Commission to the court. The court has no power to review the merits of the Commission's decisions. The only role of the court is to decide whether the Commission acted according to law in arriving at its decision.

In the author's view deference is suitable for certain issues involving expertise; however, acting in accordance with law includes acting constitutionally, therefore, correctness is the standard of review for constitutional issues.

[85]*Eldridge v. British Columbia (A.G.)*, [1998] 1 W.W.R. 50 (S.C.C.) [hereafter *Eldridge*].

Justice LaForest carefully distinguished the obligation to provide a set package of free services evenly to all persons, from the obligation to provide a specific service desired by particular groups of patients with particular needs:

> The appellants do not demand that the government provide them with a discrete service or product, such as hearing aids, that will help alleviate their general disadvantage. Their claim is not for a benefit that the government, in the exercise of its discretion to allocate resources to address various social problems, has chosen not to provide. On the contrary, they ask only for equal access to services that are available to all. The respondents have presented no evidence that this type of accommodation, if extended to other government services, will unduly strain the fiscal resources of the state. To deny the appellants' claim on such conjectural grounds, in my view, would denude s. 15(1) of its egalitarian promise and render the disabled's goal of a barrier-free society distressingly remote.
>
> Viewed in this light, it is impossible to characterize the government's decision not to fund sign language interpretation as one which "reasonably balances the competing social demands which our society must address" [86]

This reluctance was evident in another case directly on point. A couple unsuccessfully sought to oblige the New Brunswick government to cover the costs associated with ICSI.[87] They argued that the exclusion of IVF and ICSI constituted a breach of s. 15 and s.7 of the *Charter*. After a review of the health insurance system for hospital services and physicians' fees, Justice Hamilton specifically concluded that while IVF and ICSI may be medically indicated to treat infertility, they are not medically required services. The court rejected the plaintiffs' characterization of the law as a distinction that denied infertile people comprehensive medical coverage effectively preventing couples with male factor infertility the opportunity to have children. The court framed the issue narrowly describing the exclusion as the refusal to cover the costs of IVF and ICSI. Justice Hamilton noted that the public

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[86] *Eldridge, ibid.* at 97-98.

[87] *Cameron v. Nova Scotia (A.G.)*, [1999] N.S.J. No. 33 (N.S. S.C.) Feb 5, 1999 [hereafter *Cameron*]. The case is discussed in detail below.

system is not totally comprehensive: many other types of medical services are not funded and many infertility services are funded. The direct exclusion was not based on the fertility of potential patients, it was based upon the choice of the medical profession not to bring them forward for funding consideration through the usual administrative channels.[88] This did not amount to discrimination. The court also rejected the claim that health care restructuring which resulted in the elimination of an independent commission to negotiate the tariff of reimbursable services breached any s.7 right to life, liberty or security of the person. The judge found "that finding public funding of particular medical services to be considered an element of the right to life, liberty or security of persons would expand the parameters of judicial review, well beyond its present scope."[89] Justice Hamilton's closing comments echo the cautionary stance referred to above: "[c]ourts should take care before interfering with an elected government's allocation of limited public funds for social programs or the medical profession's determination of health priorities."[90]

Accordingly, it will be difficult for groups of patients to force governments to provide free access to specific services to alleviate specific conditions. However, success may depend upon the manner in which the issue is characterized. If one argues that the basic bundle of services available to all Canadians includes access to medical services enabling parenthood of healthy children, then the provision of assisted conception is merely a means of ensuring equal

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[88]Because of this holding the judge did not address whether infertility constituted a disability as an impairment of a natural human function similar to impairment of hearing; or, whether infertile persons otherwise constituted an analogous group who suffer prejudice and social disadvantage and ostracism.

[89]*Cameron, supra* note 87 at para 160.

[90]*Cameron, supra* note 87 at para. 166-171.

distribution of services to accommodate parenthood. In other words, ARTs simply constitute a necessary component of the provision of the right to procreate or to parenthood that are available to all regardless of fertility or social situation. It is probably more reasonable to characterize ARTs as distinct services which will help alleviate the problems or obstacles of certain patient groups: those who are infertile, lack a fertile partner or possess genetic characteristics which they do not wish to pass on to their children. This latter type of claim of a right to specific services is very likely to be met with the typical judicial reluctance. While the entitlement to free comprehensive health care is firmly entrenched in the public psyche, it is not entrenched in law. It appears that neither a general obligation to provide medical services nor an obligation to provide specific essential health services exists under the Canadian Constitution.

Even if health care is an entrenched entitlement, it does not necessarily follow that the right to health care includes a positive entitlement to ARTs. Similarly, even if some ARTs were found to constitute medically necessary services, that would not necessarily guarantee all potential users access to all ARTs. While the importance of procreation is undeniable, it would be difficult to establish that many forms of assisted reproduction are procedures required to alleviate illness in accordance with the traditional concept of health care[91] or even within the broader *Canada Health Act* definition of "medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or

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[91]For a discussion of the *Charter* and rationing within Canada health care system see Rivet, *supra* note 69 at 26-38. Judge Rivet suggests that IVF is not medically necessary at 32.

disability."[92] The difficulty of proving that ARTs constitute medically necessary services will increase as the demand increases and the services are used in novel situations and for novel purposes such as by fertile individuals seeking to extend the current limits of human reproduction, to overcome the lack of a sexual partner, to enhance the genetic characteristics of their children or to avoid the burdens of physical pregnancy. As noted by the RCNRT in *Proceed with Care:*

> Some have argued that the Charter can be interpreted as imposing an affirmative duty on the state to make new reproductive technologies available, so that those who are unable to become parents in the usual way can enjoy the same reproductive "rights" as other members of society. It is highly unlikely, however, that the courts would uphold such claims, given the broader social interest in providing basic health care for all Canadians and the existence of finite resources with which to do so.[93]

2. Accessibility - Rights of Access to Existing Programs

Absent a positive entitlement to ARTs (either within or independent of a right to health care services), the *Charter* may still affect the provision of reproductive services and patient/physician relationships. If the government elects to implement either an affirmative or prohibitive policy to govern assisted conception, the policy itself must conform to the *Charter*. Within the public health care system, the *Charter* applies both to constituent statutes and to decisions of delegated authorities which implement government policy. In *Eldridge* the Supreme Court of Canada confirmed that hospitals must conform to the *Charter* in implementing the government object of providing medically necessary services and that the

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[92] *Canada Health Act*, R.S.C. 1985, c. C-6, s. 2.

[93] *Proceed with Care, supra* note 44 *at 64*.

benefits of the public program must be distributed equally and in a manner that does not violate the rights to life, liberty and security of the person.[94] These comments would also apply to any regulatory and criminal laws which restrict access to ARTs in the public or private medical context.

Section 7 could be invoked to attack access criteria or limitations contained within laws or implemented by entities carrying out the government policy, particularly if penal sanctions were also used in the statues. In *Morgentaler(No.2)* the Supreme Court of Canada held that criminal laws limiting access to abortion could create great stress and endanger a woman's health for reasons unrelated to her own priorities or aspirations. The interference with bodily integrity and risk to health was recognized as part of the right to security of the person under s.7.[95] The Law Reform Commission of Canada has suggested that a similar argument could be made with respect to the denial of infertility treatments, particularly if implemented in the form of criminal prohibitions.[96] Section 7 could also be invoked to strike down overly vague restrictions.

In addition, the constitutional prohibition against discrimination under s. 15 may invalidate laws which exclude certain subgroups of patients based upon the enumerated and analogous grounds including age, genetic or other disability, sexual orientation, or marital status. The

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[94]*Eldridge, supra* note 85.

[95]*Morgentaler (No. 2), supra* note 66 per Dickson J. at 55-56, Beetz J. at 195 at 81, Wilson J. at 173. Recall that Madame Justice Wilson also held that the prohibition violated s.7 right to liberty.

[96]*Medically Assisted Procreation, supra* note 52 at 79.

constitutional validity of restrictions on access based upon other criteria such as demonstrable parenting ability, living arrangements and medical indicators is less certain. Currently the Supreme Court of Canada is divided on the interpretation of s. 15 and its relationship to s. 1. This division appears in two cases released simultaneously which were related to discrimination on the basis of marital status and sexual orientation (*Miron v. Trudel*[97] and *Egan v. Canada*[98] respectively).While the justices agreed that marital status and sexual orientation are analogous grounds,[99] they were divided on whether legislation drawing this distinction violated s.15. In the former case legislation was struck down, while in the latter it was upheld. A slim majority suggested that a distinction on either of these grounds establishes a s. 15 violation, while a minority of the Court found that s.15 could be breached only if it is established that a distinction is "internally irrelevant" to the functional values underlying the statute.[100] The minority argued that if every distinction violates s. 15, then the judiciary will usurp the constitutional role of elected officials to make legislative choices by continually calling for retrospective policy justification.[101] While it is uncertain which view of s.15 will prevail, recent cases, including *Cameron v. Nova Scotia (A.G.)*[102] seem to follow the

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[97]*Supra* note 62.

[98]*Supra* note 63.

[99]*Miron v. Trudel, supra* note 62 at 718; *Egan, supra* note 63 at 622. In *Egan* the majority commented that the parties had agreed that sexual orientation constituted an analogous ground. Later in *Vriend v. Alberta, supra* note 71 the Court affirmed that sexual orientation is an analogous ground.

[100]Justice L'Heureux Dube alone employed a third methodology.

[101]*Egan v. Canada, supra* note 63 at 622.

[102]The court then adopted the two step approach propounded in *Vriend v. Alberta, supra* note 71 at 287 (S.C.C.). This was the same approach adopted by Justice MacLachlin in *Miron v. Trudel,* [1995] S.C.R. 418 at 485*ff.* First one examines whether the law creates a distinction based on a personal characteristic and then whether the distinction results in discrimination.

majority approach. Practically, the placement of the onus to prove or disprove that a particular restriction is discriminatory may determine success. If the minority view is adopted, it will be more difficult to invalidate laws as the individual applicant will have to prove internal discrimination. If the current majority prevails, then the government will be called upon to prove some of the stereotypical and discriminatory assertions about parenting ability inherent in typical statutory limitations.

Miron and *Egan* create additional uncertainties with respect to s.15. In *Miron* five justices held that a law proscribing the terms of private insurance contracts violated s.15 by excluding nonmarried couples from coverage. Further, they held that the violation could not be saved by s. 1. While laws to protect stable family units and reduce economic hardship caused by the injury of an adult partner in a family unit were a pressing concern, marital status was not a reasonable means to determine eligibility and achieve this objective. The impairment was not minimal as the law was under inclusive. By contrast, in *Egan* the Court upheld provisions of the federal *Old Age Security Act*[103] which excluded public spousal benefits for homosexual couples. Mr. Justice LaForest[104] found that the rule did not constitute a violation of the fundamental values of the *Charter* because the law was designed to extend benefits to "the social unit that uniquely has the *capacity* to procreate children and generally cares for their upbringing .. the only unit that expends resources to care for children on a routine and sustained basis."[105] Five justices agreed that s.15 had been violated. One of the five, Mr.

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[103]R.S.C. 1985, c. O-9.

[104]With the concurrence of Lamer, C.J.C., Gonthier and Major JJ.

[105]*Egan v. Canada, supra* note 63 at 626 [emphasis added].

Justice Sopinka, held that the violation was justified under s. 1. In his view, the government should be allowed some flexibility in extending social benefits and should not be required to be instantly proactive given that social acceptance of homosexual couples was a novel concept. Because of Justice Sopinka's s.1 analysis the law was upheld. The other four justices (now the minority) held that the law failed the proportionality requirements under s.1. First, the exclusion of same sex couples was not rationally connected to the objective of creating a social security net for elderly couples as it was not rational to alleviate poverty for only part of a group based on an unconstitutional distinction. Further, three judges noted that the extension of benefits to eligible gay and lesbian couples would not involve a significant intrusion into Parliament's budgetary decision-making.

Two other recent cases involving lesbian couples suggest that access restrictions based upon marriage or sexual orientation may not withstand constitutional scrutiny. First, in *Re K.*[106] the Ontario Provincial Court modified the definition of spouse in family legislation to allow same sex couples to adopt their children. Second, in *M. v. H.*[107] a majority of the Ontario Court of Appeal ruled that statutory definitions excluding homosexual couples from the support laws applicable to unmarried cohabiting heterosexual couples were unconstitutional.[108] The majority of the Court of Appeal held that laws providing for equitable resolution of economic

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[106](1995), 23 O.R. (3d) 679 (Ont. Prov. Div.). This case involved applications by lesbian couples who jointly applied to adopt their respective children. All of the children were conceived after mutual consent through AI and were subsequently cared for equally by both mothers. The court emphasized that these families were able to meet their children's needs as well as heterosexual couples. The case is discussed in detail below.

[107](1996), 31 O.R.(3d) 417 (C.A.); leave to appeal granted April 24, 1997 [1997] S.C.C.A. No. 101 (QL). The appeal was heard March 18, 1998 and the decision is on reserve at the time of writing.

[108]To remedy the breach, the court adjusted the definition of spouse to include homosexual couples who otherwise meet the requirements of the legislation.

disputes that arise on the dissolution of intimate relations between individuals who have been financially interdependent should apply to both same sex and opposite sex couples. Further, the exclusion of same sex couples could not be rationally connected to the object of the act as required by s. 1 of the *Charter*. The Court held that the evidence was overwhelming that cohabitation between partners who have intimate relationships, regardless of sexual orientation, creates emotional and financial interdependencies and the same need for dispute resolution upon breakup. Thus the evidence supported the position that the inclusion of same-sex relationships would only serve to further the desirable goals of the legislation.

Given the deep division about the *Charter* and the respective roles of the legislatures and the judiciary, it is difficult to predict whether a statutory access limit would survive a constitutional challenge. Some restrictions may be more easily justified than others. For example, it may be easier to restrict access to extremely costly, less successful procedures such as ICSI which are likely to assist only a small proportion of patients. Similarly it may be easier to limit access to services intended to extend procreative ability beyond "natural" age limits or to enhance offspring, rather than services intended to overcome a medical problem which has resulted in infertility. Restrictions based on marital status would most certainly fail. Exclusions of single women and homosexual couples would also be suspect given that in the family law areas of adoption and spousal support under-inclusive laws are being successfully challenged. A Supreme Court ruling in *M. v. H.* together with the trend to enact more inclusive statutes may soon settle this issue. However, ARTs regulation is particularly sensitive as the very purpose of ARTs in some cases is to enable the procreation of children in nontraditional family relationships - a notion which squarely undercuts the unique aspect

of heterosexual relationships cited by Mr. Justice LaForest in *Egan* to justify limiting benefits to traditional families only.[109]

3. The Rights of Others and Clashes of Entitlements.

Additional constitutional issues are raised by the introduction of third parties into the private area of reproduction. Thus far this constitutional discussion has focused upon government regulation from the prospective of potential service users.[110] Restrictive laws may also affect the rights of providers to professional autonomy and professional survival.[111] However, providers' rights are not necessarily coexistent with patient rights. Laws which preserve personal conscience and professional autonomy may conflict with users' access entitlements.[112] Some ARTs raise even greater potential for competing rights. For example, surrogacy creates a situation where the participants' rights can be complementary (all parties will be similarly interested in reducing access restrictions placed upon surrogates) or conflicting (parties may disagree over the enforceability of a surrogacy agreement). Ironically, the interests that the government is most likely to cite to justify interference with access are those of the very potential children who, under Canadian law, are the only participants lacking constitutional rights.[113] Some suggest that in the field of family relationships individual

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[109] *Egan v. Canada, supra* note 63 at 625-626.

[110] For a discussion of the rights of other participants see Jackman, *supra* note 45 at 29-41.

[111] See Casey, *supra* note 29 at 3-16 - 3-23 and *Wilson v. B.C. (Medical Services Commission)* (1988), 53 D.L.R. (4th) 171 at 190; leave ref. [1988] 2 S.C.R. vii.

[112] See the discussion below of *Potter v. Korn* (1996), 22 B.C.L.R. (3d) 163 (B.C.S.C.).

[113] *Winnipeg Child and Family Services (Northwest Area) v. D.F.G.*, [1998] 1 W.W.R. 1 (S.C.C.) is the most recent affirmation that fetuses are not legal persons and therefore are not entitled to constitutional protection.

rights claims tend to complicate matters and divert policy formulation from the true issues and, therefore, should be subrogated to family law principles.[114] This view may also affect the framework within which legal analysis proceeds and ultimately alter the impact of the *Charter* on regulation of ARTs and patient/physician relationships.

D. Impact of Provincial Human Rights Legislation on the Provision of Health Care Services and New Reproductive Technologies

Human rights laws prohibit discrimination within certain protected spheres of activities which usually include employment, housing and services offered to the public. These laws also provide protection against discrimination upon specified grounds only. [115] These grounds vary from province to province, but the Supreme Court of Canada has ruled that the benefits of human rights laws must comply with the *Charter* and they have read in s.15 grounds.[116] Unlike the *Charter*, provincial human rights laws apply only to the issue of accessibility, they cannot be used to found a positive claim to availability. The acts cannot be used to support the claim that ART programs must be implemented if none exist. However, human rights legislation may apply in situations where the *Charter* does not, as for example to the selection policies of entirely unregulated private programs which offer services to the public. Therefore much of the prior discussion regarding constitutional guarantee of equality in access to ARTs will apply in the private treatment setting.

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[114]Stenger, *supra* note 56.

[115]For example, in Alberta the *Human Rights, Citizenship and Multiculturalism Act*, R.S.A. 1980, c. H-11.7. prevents denial of any goods, services, accommodation or facilities that are customarily available to the public, or discrimination with respect to any goods, services, accommodation or facilities that are customarily available to the public, because of the race, religious beliefs, colour, gender, physical disability, mental disability, ancestry, place of origin, marital status, source or income or family status of that person or class of persons.

[116]*Vriend v. Alberta*, *supra* note 71.

E. Health Care Policy and Regulation in Canada

Historically health was considered a private matter requiring minimal public involvement and only at the most local levels of government. Over time Canada has moved from a residual approach which emphasized private market involvement and the individual and family responsibility, to an institutional approach with greater reliance upon government involvement and less emphasis upon private markets. With this swing, providing necessary health services has become a defining element of Canadian society. Both provincial and federal governments have developed increasingly complex health care policies and enacted laws which greatly influence the delivery of services and all patient/physician relationships. This public model is deeply ingrained in the public expectations and has shaped health policies adopted by regulators. At the same time the public and the regulators have become more suspicious of private involvement in health services. However, with fiscal and other constraints, health policy reform momentum now seems to be moving back towards a residual approach. There is also a strong Canadian tradition of deference to the medical profession and of allowing the profession to regulate the provision of treatment and the course of patient/physician relationships with the courts playing a restrained remedial role triggered by individual disputes. Health care is currently provided in a mixed system with public and private components. By law, the provincial governments finance basic medical services and hospital care. Supplementary services and services not covered under the public system are available in a private market.

1. Federal Regulation

Canadians did not always enjoy a comprehensive, public health care system. Until the 1950's,

health care was largely left to the private market, religious organizations, charitable organizations and municipalities. Across Canada health legislation was patchy and diverse. In 1946, the federal government first proposed a national social security plan with four cornerstone guarantees: high stable family incomes, income protection for the unemployed and the unemployable, financial security during old age and comprehensive health care. In return for exclusive entitlement to personal and corporate income tax revenue and succession tax revenue, the Federal Government offered to establish a national health service with a regional system below it at the provincial level to be serviced by salaried physicians. The plan was well received by the public, interest groups and the medical profession. However, the misaligned constitutional jurisdiction over health care and financial resources created an unpassable political barrier.[117] Several years later, the Federal Government tried again in a two stage process to use its financial power to replace the private system with a new national system under which the provincial governments would become the sole purchasers of hospital services and medical care. First, in 1957 the Federal Government enacted the *Hospital Insurance and Diagnosis Services Act.*[118] Under this statute the Federal Government agreed to bear half of the costs of all hospital construction and hospital services undertaken by the individual provinces if the provincial programs were universal in coverage of the population. Second, in 1966 the Federal Government introduced the *Medical Care Act*[119] despite the

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[117] The political and economic price tags of the proposal were too much for both Quebec and Ontario and without their support the deal failed.

[118] S.C. 1957, c.28.

[119] S.C. 1966-67, c.64.

protests of some provinces, the Canadian Medical Association[120] and the private insurance industry. This open-ended plan provided that the Federal Government would share half of the costs of physicians services for any provincial plan which was publicly administered, comprehensive, portable and universal. This scheme was intended to make medical need replace financial means as the main determinant of access.

In 1966, the Federal Government consolidated many categorical cost sharing programs, including medical and hospital coverage, into the last open ended cost sharing program, the Canada Assistance Plan.[121] Under this program, the Federal Government matched provincial expenditures for specific social and health care programs.[122] The financial support was intended to cover the basic requirements of life in addition to certain specified programs including medical services and community and continuing care. This program maintained the steering effect of earlier programs. It reinforced the unfortunate tendency to over-build capital infrastructure and to tailor projects to satisfy funding criteria. It also further entrenched the expensive physician and hospital dominated model of health care.

In response to concerns about the soaring cost of health care, slow economic growth, wage and price inflation, and falling tax revenues, the Federal Government took steps to limit its

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[120]The medical profession had exercised a great deal of financial control before the public health care system was introduced as professional associations often ran health insurance programs. Ultimately physicians accepted the "medicare deal" as a trade off between the entrepreneurial autonomy and the financial risks associated with practising medicine.

[121]S.C. 1966-67, c.45.

[122]The program covered special vocational programs, welfare programs for natives on reserves and also general assistance programs.

financial commitment to health care and other social programs in the early 1970s.[123] The *Federal-Provincial Fiscal Arrangements and Established Programs Financing Act* ("EPF")[124] was passed in 1977 capping the federal obligation to finance health care in Canada by switching from a cost-sharing program to a block-funding program. The EPF grouped social programs, health services, and post-secondary education together into a single funding package and left the distribution of the funds amongst the various programs to the discretion of the provinces.[125] During the late 1970's and early 1980's, provincial governments also felt financial burdens and began to revise their health care systems. To shift the burden of these costs, the provinces, including Alberta, began to allow user fees and double billing, and to de-insure certain services. In response, in 1984 the Federal Government passed the *Canada Health Act*[126] (the *"CHA"*) which consolidated the *Hospital Insurance and Diagnostic Services Act* and the *Medial Services Act* and clarified the conditions of eligibility for federal funding. Under the *CHA*, all provincial health programs were required to satisfy five conditions: comprehensiveness, public administration, universality, portability and accessibility.[127] The *CHA* specifically prohibited user fees and extra billing of insured services.

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[123]See M. Taylor, "The Canadian Health Care System, 1974-1984," in R. Evans & G. Stoddart, eds., *Medicare at Maturity: Achievements, Lessons and Challenges* (Calgary: University of Calgary Press, 1986) 3.

[124]S.C. 1976-77, c.10.

[125] The Federal Government transferred tax points to the provinces to enable them to finance their programs and limited its own contributions to transitional equalization payments and incremental transfers tied to the growth of the gross national product for Canada rather than provincial spending.

[126]R.S.C. 1985, c.C-6.

[127] The five criteria are:

1. Comprehensiveness: the programs must cover all medical services determined to be necessary by physicians as well as an explicit list of hospital services;
2. Public Administration: the program must be run by the government on a nonprofit basis;
3. Universality: the program must be available to all of the residents of the province;
4. Portability: the program must provide coverage to residents temporarily out of the province; and,

The *CHA* included punitive provisions to discourage these charges.[128] Since 1977, the Federal Government has continued through a series of laws to adjust the funding formula and to decrease its financial obligations increasing the fiscal pressures for the provinces.[129] Over the same time period, the Federal Government has amalgamated even more types of transfer payments to prolong its ability to "punish" provinces who adopt health care systems that violate the *CHA* principles. In early 1999, the Federal Government committed additional funds to provincial health care programs and all the governments renewed interest in national health care standards through the creation of a social union.

The *CHA* does not apply to all health care services offered in Canada. The federal act and its equitable principles do not apply to nonessential or nonbasic services provided within the private health care market. In addition, physicians may elect to operate outside of the public system and private insurers may provide financial coverage without any retribution for services not covered within the provincial scheme. It is difficult to define the limits of essential services within the *CHA* system, the act does not require the provinces to cover the cost of specific ARTs, fertility drugs or sperm (some ARTs fall within the public system while others are excluded.) In addition to conditional funding of medical services and hospital programs,

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5. Accessibility: services must be provided on a uniform basis and upon uniform conditions that do not preclude access to any group.

[128]In the event of double billings, Federal transfers may be reduced dollar for dollar in an amount equal to the entire cost of particular services.

[129]The Supreme Court of Canada affirmed the ability of the Federal Government to limit its expenditures on health and other social programs as an austerity measure see *Reference Re Canada Assistance Plan (B.C.)*, [1991] 2 S.C.R. 525. These federal cash transfers are gradually falling and it was once projected that before the year 2000 certain provinces including Alberta might be forced to finance the public system without any assistance from federal cash transfers. See P. Boothe & B. Johnston, *Stealing the Emperor's Clothes: Deficit Off-loading and Nationals Standards in Health Care (Commentary No. 41)* (Toronto: C. D. Howe Institute, 1992).

over the years the federal government has exercised control over patient/physician relationships through laws regulating pharmaceuticals and medical devices. These laws were enacted pursuant to the federal authority over public health to protect the consuming public. They affect the availability of fertility drugs and the importation of human sperm in particular.

2. Provincial Regulation

As federal steering and support dwindles and other pressures rise, many provinces have reformed their health care systems. The systems vary from province to province and are continually evolving. However, there are some common elements. Within each province the legal framework governing health services is found in a varied collection of statutes and regulations covering three categories: financing, delivery and professional regulation.[130]

All provincial systems include a publicly financed insurance scheme that complies with the *CHA* to cover the costs of delivering medically required services without charge at point of service.[131] The laws which create these insurance systems do not necessarily specifically define

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[130]Alberta's system is typical, under the *Alberta Health Insurance Act*, R.S.A. 1980, c.A-24, s.6 the Health Minister is required to administer and operate a nonprofit plan to provided benefits for "basic" health services only. (In 1995, Grant Mitchell, then leader of the opposition introduced Bill 201, *Regional Health Authorities Amendment Act*, 3rd Sess., 23rd Leg., Ab., 1995. It would have altered these responsibilities by legally obliging the Regional Health Authorities to act in a manner consistent with the five federal principles set out in the CHA). In the early 1990s, the province switched to a devolved system in which Regional Health Authorities have replaced more than 200 local management boards which previously governed various individual institutions and programs. Under this system, Regional Health Authorities receive global funding and are responsible for selecting regional priorities and allocating resources within that budget *(Regional Health Authorities Act*, S.A. 1994, c.9.07, s.5(a)). The Minister has the final authority, subject to the cabinet, to determine whether a particular service is medically required and therefore insured: *Alberta Health Insurance Act*, ss. 4(2) and 6(e) The provincial government pays the majority of physicians directly on a fee for service basis in accordance with a schedule negotiated with the provincial medical association.

[131]In some provinces the programs are financed only through tax revenues, but in other provinces (including Alberta) the program is also supported by insurance premiums. For an outline of the provincial insurance systems and reform initiatives in the mid 1990s see G. Schellenberg, "Provincial Initiative to Control Health Care Costs"

all insured services, but they often include exclusions or mechanisms to determine covered services and to set specific reimbursement rates for hospital services and for physicians' services.[132] Apart from excluding certain procedures, the health care system relies heavily upon the professional judgement of physicians to determine what services are medically necessary. While some aspects of infertility treatments such as trips to a general family physician to obtain fertility drugs or surgery to repair damaged fallopian tubes are covered in the public system, not all ARTs are provided free of charge. The trend not to insure ARTs is likely to continue due to the high costs of the technical procedures and the perception that ARTs do not fall within the core bundle of basic or medically necessary services.

Provincial statutes governing health care delivery are more diverse than provincial laws creating the basic insurance schemes. These statutes delegate the responsibility to deliver services and allocate resources to different entities such as hospital boards or regional health authorities. Most provinces have enactments that provide for internal governance of these authorities and for the licensing of specific classes of facilities. Delivery laws typically address issues such as physician's privileges, confidentiality and the use of patient records. Some provincial statutes include procedures to deal with patient complaints. While some enactments impact treatment transactions in specific areas such as mental health, the statutes do not

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Research Papers prepared for the Canadian Bar Association Task Force on Health Care: Background papers for What's Law Got To Do With It?: Health Care Reform in Canada (Ottawa: the Association, 1994).

[132]For example, in British Columbia, the *Medicare Protection Act*, R.S.B.C. 1997, c.289 sets up the general system and the *Medical and Health Care Services Act Regulation*, B.C. Reg. 426/97 sets out the system for benefits, lists certain exclusions and delegates the authority to determine what benefits will be provided to the Medical Services Commission. See J. Morris, *Law for Canadian Health Care Administrators* (Toronto: Butterworths, 1996) at 23-39 for a brief description of the provincial insurance schemes.

generally set out specific standards regarding delivery of services such as eligibility of patients or professional treatment protocols, traditionally these issues are left to the profession.

In the third category of professional regulation, provincial laws delegate the authority to provide practice standards and directions and to set up administrative mechanisms to control registration, licensing and discipline to the respective provincial Colleges of Physicians and Surgeons.[133] These bodies set ethical standards to regulate the conduct of their members in providing treatment. They have a legal responsibility to ensure compliance with professional standards. These self-regulating bodies may impose several consequences for substandard behaviours including: warnings, fines, practice restrictions, suspensions and erasures.[134] Their decisions are usually subject to internal appeals and ultimately judicial scrutiny through judicial review proceedings or statutory appeals.[135] However, if issues involving medical expertise are at issue, the courts are not likely to scrutinize these decisions too heavily due to limitations in the statutes allowing recourse to the courts and to the administrative law principle of general deference allowed to administrative bodies with professional expertise.[136]

3. Summary on Health Care Policy and Regulation

Over the past 40 years the federal government has provided conditional financing to the

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[133]*Medical Profession Act*, R.S.A. 1980, c. M-12, s. 3.

[134]*Ibid.* ss 56-57.

[135]Under the *Medical Profession Act*, R.S.A. 1980, c.M-12 the decision of the council may be appealed to the Court of Appeal s.58 and the Court has rather broad powers to make findings, confirm or quash a decision or punishment and refer the matter back to the council for further consideration s. 61.

[136]See for example *Cameron v. Nova Scotia (A.G.)*, *supra* note 87.

provinces that as single payors have endeavoured to deliver a core of medically required services. Canadians have become strongly committed to the just provision of comprehensive health care services free at the point of service.[137] The development of health policy and regulation reflects this public commitment. However, not all services are insured. Within this system, physicians have enjoyed significant autonomy over the patient/physician relationship and the mix and volume of services which they provide. They control the majority of health expenditures, they determine both what services are medically necessary and what patients need those medical services. Furthermore, physicians are free to opt out of the insurance scheme or to provide services outside the scope of medically necessary or basic in the private market setting. Physicians providing treatment services remain subject to legal controls outlined in this chapter including, common law obligations, statutory obligations, and mandatory and voluntary professional self regulation. Provincial governments have not enacted statutes to directly alter the patient/physician relationship or to set specific terms such as conditions of eligibility for treatment. For the most part, the task of professional regulation has been left to the provincial Colleges of Physicians and Surgeons.[138]

F. Canadian Laws and Legislative Initiatives Specific to Assisted Reproduction

1. Provincial Legislation

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[137]"Canada's public heath insurance system was established on two fundamental egalitarian principles: that is, health care need must be addressed regardless of ability to pay and there must be equitable access to necessary health care services." D. Angus et al., *Sustainable Health Care for Canada: Synthesis Report* (Ottawa: Queens' University of Ottawa Economic Project, 1995) at 22.

[138]See M. Dohler, "Physicians' Professional Autonomy in the Welfare State: Endangered or Preserved?" in G. Freddi & J. Bjorkman, eds., *Controlling Medical Professionals: The Comparative Politics of Health Governance* (London: Sage Publications, 1989).

Several Canadian governments and law reform organizations have studied ARTs, although to date these reform initiatives have failed to yield significant legislative changes. No provincial laws deal comprehensively with the substantive issues involved in the delivery of ARTs. Three types of statutes enacted in the common law provinces and territories touch upon assisted reproduction: public health care insurance laws, human tissue and organ donation laws, and child and family relations laws. The first two types of laws generally exclude ARTs and the related materials from existing legal regimes, while provisions in the third category outline the legal obligations and rights of families with children produced by nonsexual means.

As outlined earlier, fertility drugs and some of the medical services provided to diagnose infertility or to facilitate artificial reproduction are excluded from coverage under many provincial health benefit plans.[139] Often these exclusions are not expressly prescribed by statute or regulation. They arise as the result of administrative policies adopted by delegated authorities. Ontario is the sole province that has covered some of the costs of IVF and that coverage is limited by regulation to three treatment cycles for women suffering infertility due to bilateral fallopian tube blockage (unless the blockage is due to prior sterilization.)[140]

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[139]E.g. IVF was never listed as an insured service in the tariff of insured services under the Nova Scotia *Health Services and Insurance Act*, S.N.S. 1992 , c.20. It was explicitly excluded in 1996. See *Cameron v. Nova Scotia (A.G.), supra* note 87.

[140]Gen. Reg. 552 s. 24(1) lists exclusions, IVF limits were added by O. Reg. 488/94, s 2(1)(2).Under the Reciprocal Interprovincial Billing Arrangements all provinces, other than Quebec, agree to cover the cost of certain procedures provided to their residents in other provinces (usually extraprovincial treatments are provided to meet an unexpected need or because a service is unavailable within the home province). Certain procedures, including IVF and AI are specifically excluded from coverage:*Cameron v. Nova Scotia, supra* note 87.

Each jurisdiction in Canada has enacted laws to govern the transfer and transplantation of human organs and tissues.[141] These enactments follow three basic models subject to minor variations.[142] They define the conditions under which donations are permissible and dictate things such as the minimum age of donation, the permissibility of posthumous donations and the procedures for donations by minors. As most acts are limited to nonregenerative tissue and body parts, they are not generally considered to apply to human sperm or even ova.[143] Some statutes, including the *Uniform Human Tissue Donation Act 1989*,[144] expressly exclude sperm, ova and human embryos or fetuses. Others go further and also exclude parts of human embryos and fetuses.[145]

In the third category, family law, some provinces have enacted remedial legislation dealing with legal parentage and support obligations for artificially conceived children who are not genetically linked to their intended parents. For example, the Newfoundland *Children's Law Act 1990*[146] deems the spouse of the mother of an artificially conceived child to be the legal

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[141]*Human Tissue Gift Act*, R.S.A 1980, c.H-12; *Human Tissue Act*, R.S.N.B. 1973, c.H-12; *Human Tissue Act*, R.S.N.S. 1989, c. 215; *Human Tissue Act*, R.S.O. 1990, c. H.20; *Human Tissue Gift Act*, R.S.S. 1978, c.H-15; *Human Tissue Gift Act*, R.S.Y.T. 1986, c.89; *Human Tissue Gift Act*, R.S.B.C. 1996, c.211; *Human Tissue Act*, R.S.M. 1987, c. H.180; *Human Tissue Donation Act* S.P.E.I. 1992, c.34; *Human Tissue Act*, R.S.N.W.T. 1988, c. H-6; *Human Tissue Act*, R.S.N. 1990, c.H-15. See also Arts. 19-25, 43 C.C.Q.

[142]Some acts permit donations by minors while others do not and the statutory age of consent varies from 16 to 19 years of age. Some statutes also include specific rules for donations of certain body parts.

[143]Nonregenerative tissue is often described as "tissue not replaceable by natural processes of repair" or "tissue in a living human body that on injury or removal does not replace itself." See *Doctors and Hospitals in Canada*, *supra* note 4 at 97-98.

[144]*Uniform Law Conference of Canada, Consolidation of Uniform Acts (1979) looseleaf, (1990) Supp.* at 22-1. Most provincial laws are based upon the earlier uniform act, *The Uniform Human Tissue Act.*

[145]*Human Tissue Act*, R.S.M. 1987, c. H180, s. 1; *Human Tissue Donation Act*, S.P.E.I. 1992, c. 34, s. 1(g).

[146]R.S.N., c.13 s.12 added by S.N. 1988, c.61 s.12 (reproduced in Appendix B).

father (subject to exceptions for lack of consent or deception). It also provides that the donor is not the legal father. A substantively identical provision was enacted in the Yukon.[147] The Civil Code of Quebec includes similar provisions regarding paternity[148] and prohibits surrogacy agreements on the basis that procreation and gestation agreements on behalf of another person are contrary to public policy, absolutely null and therefore unenforceable.[149] It also provides that nominative (identifying) information is confidential, but may be obtained through medical intermediaries in exceptional circumstances involving a serious injury to the health of the progeny or their descendants.[150]

The proposed *Uniform Child Status Act*[151] goes further than filiation statutes. Based upon an expanded definition of assisted conception, this act applies to a larger number of procedures than other statutes. It provides more detailed rules about legal parentage and addresses the interests of both the legal father and the legal mother. It affirms the act of birth as the defining criterion for legal maternity. The act also prohibits commercial transactions involving sperm and ova. Violations are subject to significant fines and imprisonment. Finally, it establishes a reporting scheme requiring physicians to provide information about

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[147]*Children's Act*, S.Y. 1986, c. 22 s. 13.

[148]Arts. 523 -540 C.C.Q. For a detailed discussion of the impacts of Quebec civil laws in general see M. Ouelette, "The Civil Code of Quebec and New Reproductive Technologies" in *Overview of Legal Issues in New Reproductive Technologies, Research Studies of the Royal Commission on New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply and Services, 1993).

[149]Art. 541 C.C.Q. provides that any procreation or gestation agreements made on behalf of another person are absolutely void.

[150]Art. 542 C.C.Q.

[151]1980, ss. 11-11.6 amended in 1991, *Uniform Law Conference of Canada, Consolidation of Uniform Acts (1979)* looseleaf, at 5-5 - 5-7. (Relevant sections are reproduced in Appendix B).

procedures, births and linking records. However, the statute is scant on details leaving broad regulation making authority to the discretion of an unspecified agency. No province has adopted this scheme.

2. Federal Legislation

Despite numerous studies into assisted reproduction and its regulation, to date only the federal government has demonstrated a willingness to enact comprehensive ARTs legislation. By international standards, Canada entered the assisted reproduction regulatory fray late. In July of 1995, the federal government requested a voluntary moratorium on certain services: sex selection for nonmedical purposes; buying and selling ova, sperm and embryos for profit; germ-line genetic alteration; ectogenesis; cloning human embryos; creating animal-human hybrids, using sperm or eggs from foetuses or cadavers; and, commercial surrogacy.[152] After this measure failed to have substantive impact, the government took two more steps to regulate ARTs.[153] In 1996, the same year that Louise Brown turned 18, the federal government passed regulations under the *Food and Drugs Act*[154] to govern the processing and distribution of semen for assisted conception services and introduced Bill C-47, *the Human Reproductive and Genetic Technologies Act* ("Bill C-47").[155]

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[152]For a critique of criminal law and the flaws in the moratorium see B. Dickens, "Do not Criminalize New Reproductive Technologies" (1996) March Policy Options 11.

[153]See Canada, Ministry of Health, *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (Ottawa: Canada Minister of Supply and Service, 1996) at 23-26 [hereafter *"Setting Boundaries."*]

[154]*Food and Drugs Act*, R.S.C. 1985, c. F-27.

[155]Bill C-47, *Human Reproduction and Genetic Technologies Act*, 2nd sess., 35th Parl.,1996 (Reproduced in Appendix B).

While Bill C-47 received much more media attention than the *Processing and Distribution of Semen for Assisted Conception Regulations*[156] that were actually enacted, the regulations go quite far to substantively regulate the provision of ARTs. The regulations deem sperm to be a drug within the meaning of the *Food and Drugs Act* and bring centres offering ARTs using semen within the existing administrative structures of the Department of Health. The regulations do not purport to address all legal and ethical issues associated with the use of ARTs. The regulations govern the use of domestic and imported semen, but do not apply to ova or embryos. The regulations are expressly limited to safety issues, particularly the risk of transmitting infectious diseases such as HIV. Their main object is to introduce enforceable national standards to minimize danger to the health of recipients, their partners and their children. They do not address other issues in patient/physician relationships, access criteria or issues raised by extracorporeal human embryos.

According to the Regulatory Impact Statement released with the regulations, the government chose to enact regulations incorporating professional guidelines over a third party accreditation scheme set up by some of the same professional bodies because those programs were voluntary and could be disregarded by processes and distributors. However, the regulatory scheme is highly deferential to medical practitioners and the current professional self-regulation model. Industry guidelines are incorporated into the regulations by reference.[157] To minimize the risks to recipients, the regulations expressly prohibit the

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[156]SOR 96/254.These regulations were enacted almost 20 years after the first federal study into artificial insemination and in response to concerns expressed by the RCNRT (Reproduced in Appendix B).

[157] SOR 96/254, ss. 1, 4 and 9 adopt CFAS guidelines respecting donor screening procedures, see below.

distribution of semen until a) it is quarantined for at least six months and does not test positive for certain types of contamination; and, b) it is determined that the donor is not a member of an excluded group.[158] All processors, distributors and physicians using semen are obliged to register with the Assistant Deputy to the Minister. These entities and individuals must also adhere to standard procedures for labelling semen samples and for maintaining linkable records enabling retrospective tracing of potentially contaminated semen. The regulations include investigation protocols and reporting procedures in the event contamination is detected. While the regulations require contamination to be brought to the attention of donors and other suppliers and distributors, there is no specific obligation to inform AI recipients.

Bill C-47 received first reading in the same month that the *Semen Regulations* came into force. It was the second phase of a three phase initiative described in the Ministry report, *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health.*[159] The preamble to Bill C-47 describes the three areas it addresses: a) grave concerns about human dignity and health and serious social and ethical issues; b) health and ethical dangers inherent in the commercialization of human reproduction and the potential to exploit women and children for commercial trade; and, c) the need to protect and promote the best interests of children affected by ARTs. The body of Bill C-47 includes three additional objectives: a) ensuring the protection of health and safety of Canadians and the safe use of human

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[158]SOR 96/254, s.4.

[159](Ottawa: Minister of Supply & Service, 1996) at 25-26 [Hereafter, *Setting Boundaries*]. The three stages involved: the moratorium announced in July 1995, the enactment of criminal prohibitions, and then the introduction of a regulatory "management scheme" for permitted technologies. Appendix A of *Setting Boundaries* sets out the rational supporting criminal prohibition.

reproductive materials for assisted reproduction, other procedures and medical research; b) ensuring appropriate treatment of materials outside the body in recognition of its potential to form human life; and, c) protecting the dignity of all persons particularly women and children.

Bill C-47 is merely a shopping list of prohibited practices including: cloning; mixing of human gametes and zygotes or embryos; germ cell therapy, using gametes obtained from foetuses or cadavers; sex selection before or after conception for nonhealth-related reasons; maintaining embryos outside the human body; creating embryos for research purposes; engaging in commercial surrogacy; acting as an intermediate for commercial surrogacy; selling, bartering, purchasing or exchanging anything for gametes, embryos or foetuses; offering to pay for any of the prohibited services; or, using gametes, embryos and sperm without donor consent. It does not prohibit ovum or embryo donations, it does not prohibit all embryonic experimentation. It does not restrict professional decisions about the creation of embryos to be used in assisted reproduction. Bill C-47 could have many other impacts as s.13 delegates broad authority to the Governor in Council to make regulations to carry out the purposes and provisions of the bill (to date no draft regulations have been released). Bill C-47 includes rather severe penalties. Any person in violation of the act (patient, donor, provider, or commercial enterprise) is liable on summary conviction to a fine of up to $250,000 and to imprisonment for up to four years, or to a conviction on indictment together with a fine of up to $500,000 and imprisonment for up to 10 years.[160] Bill C-47 is essentially an intrusive penal statute which deprives individual rights in a draconian manner, purportedly

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[160]Bill C-47, *supra* note 155 s.8.

in the interests of women and of unborn children even when the law has not traditionally recognized the legal status of unborn children, fetuses or embryos. The Bill was heavily criticised as blunt and overly punitive by many groups.[161] It died after second reading and has yet to be reintroduced in either its original or a modified form. The Minister of Health has indicated that a new statute is forthcoming.

Criticism was also directed toward the third phase of the government plan, the establishment of a regulatory regime to control acceptable new reproductive and genetic technologies and balance individual and collective interests in a flexible responsive way.[162] In its 1996 report *Setting Boundaries*, the federal government endorsed the establishment of an independent regulatory agency to develop standards for the use of reproductive technologies and materials, issue licenses and ensure compliance with the regime. As with the federal *Semen Regulations*, the government took the position that a self-regulatory model was not sufficiently coercive - an independent agency was required to ensure compliance and to safeguard the other interests.[163] The government proposed to combine the regulatory regime with Bill C-47 in a single comprehensive statute. The proposed regulatory regime was to be built upon a set of ethical principles derived from the RCNRT: balancing individual and collective interests; ensuring equality while recognizing the disparate impact of this

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[161] See *Canadian Medical Association Brief on Human Reproductive and Genetic Technologies Act*, presented to the Subcommittee on Bill C-47 at Ottawa, Ontario January 24, 1997; *Canadian Bar Association Brief on Bill C-47 Human Reproductive and Genetic Technologies Act* (Ottawa: the Association, 1996); *National Association of Women and the Law Response to Bill C-47 and Working Document on New Reproductive And Genetic Technologies: "Setting Boundaries, Enhancing Health"* (Ottawa: the Association, April 1997).

[162] *Setting Boundaries, supra* note 159 at 12. The document was released after consultation with stakeholders.

[163] *Setting Boundaries, supra* note 159 at 27.

technology on women; protecting vulnerable groups (particularly women, children and people with disabilities); ensuring the appropriate use of medical treatment; preventing the commercialization of reproduction and reproductive materials; and, maintaining accountability of individuals and governments.

The proposed regulatory agency would advise the Minister about general policy issues. It would be empowered to issue and revoke licenses, ensure compliance through inspection and investigation and apprise licensees of important developments. The agency would also inform other professional bodies of licence breaches and enjoin licensees from continuing to violate the statute. Licenses would only be issued to nonprofit entities and to individual licensees to ensure that providers would only receive reasonable levels of compensation. Following the trend to more open systems and the need for more comprehensive record keeping systems, the agency would maintain four information registries: a donor/offspring registry to collect information about donors and the health of their offspring; a fertility treatment registry tracking the location of providers and other information about success rates to enable informed choices; a registry of fertility drug surveillance, and a registry to track the short and long term health of the children born using these procedures and to evaluate the procedures. Under this regulatory model, a great deal of power would remain with the government as the Governor in Council was delegated broad regulation-making powers concerning, but not limited to:

> the collection, processing, distribution and use of human reproductive materials (sperm, eggs and embryos) in providing assisted human reproductive procedures (including DI and IVF) and in conducting medical research. It would also deal with the collection, processing, distribution and use of human fetal tissue in

providing medical procedures and in conducting medical research.[164]

Violations of the regulatory aspects of the legislation would be subject to the criminal sanctions set out in Bill C-47 and prosecutorial control would remain with the Attorney General of Canada.

It is not clear what legislative action the government may actually take. *Setting Boundaries* is a preliminary document which lacks specifics. It is not internally consistent pointing at different times to public consensuses and pluralities on key issues. The report does not provide a rationale for the restrictive regulatory model. *Setting Boundaries* does not examine the constitutional basis for federal involvement, it simply asserts that federal involvement is required for health measures in areas that will benefit from a coordinated national scheme. The report acknowledges that the provinces have a large role in family law issues and in health service delivery. It provides that the regulatory provisions (other than the criminal prohibitions) would be suspended in "any province or territory with controls substantially the same as, but not necessarily identical to, the federal legislation in substance and enforcement."[165] The report also contemplates a much larger scale policy to address the full spectrum of reproductive rights as it stresses the need for a coordinated framework to deal with genetics and sexual and reproductive health generally.

In addition to these initiatives, some specialized national groups have assumed the

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[164]*Setting Boundaries, supra* note 159 at 27

[165]*Setting Boundaries, supra* note 159 at 33.

responsibility to set ART guidelines and standards. The Society of Obstetricians and Gynaecologists of Canada ("SOGC") and the Canadian Fertility and Andrology Society ("CFAS") recently developed joint policy statements applicable to ARTs.[166] An earlier version of the guidelines were incorporated by reference into the federal *Semen Regulations*. The Canadian Council on Health Services Accreditation ("CCHSA") is a private accreditation agency that acts in conjunction with many professional agencies to establish accreditation standards and procedures for many types of health facilities.[167] The agency is working together with the SOGC and CFAS to set guidelines for centres providing ARTs. In addition, if a facility provides procedures that are considered to be experimental, then its activities fall within the existing regulatory system involving research ethics boards and federal guidelines. The Medical Research Council, the Social Services and Humanities Research Council and the Natural Science and Engineering Research Council have just completed a Tricouncil Policy Statement on *Ethical Conduct for Research Involving Humans*[168] which addresses research involving human gametes, embryos and foetuses. Applicants seeking funding from the Councils must certify that their projects comply with the provisions of this code. The councils are all federally incorporated entities constituted to promote and in some cases perform research; to disseminate information; and, to advise the federal Minister on recent

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[166]These guidelines were expected in the fall of 1998. They were recently completed and are currently being published in parts in the Journal of the Society of Obstetricians and Gynaecologists of Canada in early 1999. They cover: Disposition of Frozen Embryos; Intracytoplasmic Sperm Injection; Medical and Genetic Screening of Sperm, Oocyte and Embryo Providers; Oocyte Transfer: Sources of Oocytes and the Nature of the Exchange; Preconception Arrangements; Pre-Implantation Genetic Diagnosis; Social Screening and Reproductive Technologies; and, Research on Human Embryos; and, Sperm Sorting for Medical and Non-medical Reasons.

[167]Some provincial laws reinforce the standards set by the CCHSA see for example Alta. Reg. 247/90 s. 34(1) under the *Hospital Act*, R.S.A. 1980, c.H-11 which states that hospitals shall strive to meet the CCHSA standards.

[168](Ottawa: Public Works & Gov't Services Canada, 1998).

developments.[169]

G. Canadian Cases Involving Assisted Reproduction

A search of reported and unreported legal case databases yielded more than 100 Canadian cases which deal with ARTs in some manner. Far fewer cases dealt solely or even primarily with reproductive services. The relevant cases are grouped into four broad categories: family law cases including marital and parental responsibility; tortious damage claims for injuries necessitating subsequent reproductive assistance; cases involving professional treatment standards; and, cases dealing with availability and accessibility.[170]

1. Family Law Cases

Family law has adapted relatively well to situations involving nonsexual reproduction even in the absence of remedial legislation. The cases involve living children and for the most part are decided on the basis of the best interests of those children, regardless of the method of reproduction. Existing laws are simply interpreted to suit this overarching purpose.

The first Canadian case to consider AI and family law was an odd 1921 decision, *Orford v. Orford*,[171] in which the judge declared AI to constitute adultery on the grounds of public

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[169]*Medical Research Council Act*, R.S.C. 1985, c. M-4; *Social Sciences and Humanities Research Council Act*, R.S.C. 1985, c. S-12; and the *Natural Sciences and Engineering Research Council Act*, R.S.C. 1985, c.N-21.

[170]One case defied categorisation. In 1994 ,the Trial Division of the Federal Court ruled that an immigration officer must consider the claim that in some other countries AI constitutes adulterous criminal behaviour in assessing whether an immigrant who has received such treatment should be allowed to remain in Canada on compassionate and humane grounds: *Sorkhabu v. Secretary of State* (1994), 26 Imm. L.R. (2d) 287 (Fed. T.D.).

[171](1921), 58 D.L.R. 251 (Ont. S.C.).

policy. During fault-based divorce proceedings, Mr. Orford sought to avoid paying spousal support by proving his wife had committed adultery. The wife admitted that during their separation she had given birth to a child of another man, but claimed that the child was conceived artificially and that the entire pregnancy had been initiated to cure a physical problem which had made it impossible for the couple to consummate their marriage. Unimpressed with the wife's testimony, Justice Orde held that the child was conceived through sexual intercourse. However, the judge continued on to discuss the nature of adultery. He determined that it had never been exactly defined, but "was always regarded as an invasion of the marital rights of the husband or the wife."[172] AI constituted adultery as it introduced foreign blood into the husband's family. In the words of Justice Orde:

> ...the essence of the offence of adultery consists not in the moral turpitude of the act of sexual intercourse, but in the voluntary surrender to another person of the reproductive powers or faculties of the guilty person; and any submission of those powers to the service or enjoyment of any person other than the husband or the wife comes within the definition of "adultery."
>
> The fact that it has been held that anything short of actual sexual intercourse, no matter how indecent or improper the act may be, does not constitute adultery, really tends to strengthen my view that it is not the moral turpitude that is involved, but *the invasion of the reproductive function....*
>
> Mr. White was driven, as a result of his argument, to contend that *it would not be adultery for a woman living with her husband to produce by artificial insemination a child of which some man other than her husband was the father! A monstrous conclusion surely. If such a thing has never before been declared to be adultery, then, on the grounds of public policy, the Court should now declare it so.*[173]

More recent decisions have been less condemning, centring upon the support obligations of

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[172]*Orford v. Orford, supra* note 171 at 257.

[173]*Orford v. Orford, supra* note 171 at 258-259 [Emphasis added].

parents and their spouses rather than the propriety of the procedures. The cases are clear - biological lineage and the means of reproduction are not governing considerations, in some cases these factors are not even relevant.[174] The means of reproduction yields to the family law principle that the best interests of the children govern dispute resolution. The courts have strained to interpret statutory provisions in a manner consistent with the social, rather than the biological, situation. Increasingly legal rights and responsibilities of parentage are assigned to the functional parents of artificially conceived children. The trend has been somewhat slower with respect to homosexual families.

In *Zegota v. Zegota*[175] the Ontario General Division Court granted parental status, access rights and support obligations to the former husband of a women impregnated by AI using donor sperm. The Court declared him to be the legal father under s.5 of the *Children's Law Reform Act*[176] regardless of any statutory provisions specific to AI. Both parents had agreed to the AI procedure and executed consent forms indicating an intention that the child would be theirs. The couple separated four months prior to the birth of the child due to the strain of infertility.[177] The wife wanted no part of the husband and frustrated his access rights. The

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[174]See for example *Richter v. Richter*, [1995] O.J. No. 4131 (Ont. C. J. Prov. Div.) (QL) where the judge decided the case just like any other custody and access decision and merely mentioned in passing that the child was produced as a result of AI. In *B.(R.A) v. J.W.E.*(1995), 418 A.P.R. 230 (N.S. Fam. Ct.) the Nova Scotia Family Law Court ruled that the boyfriend of a mother of a child allegedly conceived by a "lay method" of AI using his sperm was deemed to be the child's legal father despite his protestations. According to the judge, the boyfriend was the biological father regardless of the method of impregnation.

[175](1995), 10 R.F.L (4th) 384 (Ont. Gen.Div.); access varied slightly on other grounds (1997), 31 R.F.L (4th) 446 (Ont. C.A.).

[176]R.S.O. 1990, c.C-12.

[177]The couple did not disclose their true marital situation at the time they applied for assistance and they were also approved as adoptive parents at the same time despite their difficulties.

Court ruled it would be cruel and damaging to the child's future to deny access to the former husband who had shown a sincere desire to be the child's father and had established a relationship with the child despite the mother's actions.

Similarly in *Low v. Low*[178] the Court affirmed the legal status of the spouse of an AI recipient. After cohabiting for a year, the couple married. Due to the husband's low sperm count, the wife received AI within months of their marriage. The marriage was troubled from the start and ended within days of the birth of the baby. Because the husband had acted as a father by supporting and visiting the child for four years, the Court recognized him as the legal father under the *Children's Reform Act*[179] and granted him access and support obligations. In the ruling, the Court noted that the term "natural" was not used throughout the statute and that the relevant sections did not explicitly require a biological or genetic link as a precondition to parenthood.

A.K. v. A.P.[180] also affirmed that children's interests and adult actions, rather than biology, determine parental rights and responsibilities. In this case the court denied parental rights for the mother's former husband. The wife wanted children. The husband did not. Due to the husband's previous vasectomy, the wife conceived using AI. The couple separated when the child was six months old at which time the father signed an agreement giving him a favourable monetary settlement and acknowledging that he was not the biological father, had not acted

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[178](1994), 4 R.F.L. (4th) 103; 114 D.L.R. (4th) 70 (Ont. Gen Div.).

[179]R.S.O. 1990, c. 12 ss. 1(1), 4, 5, 8.

[180](1996), 91 O.A.C. 273 (Ont. C.A.).

like the father and would not have access or support obligations. He also agreed that he did not have or want independent legal advice. The Court of Appeal denied his access claim ruling that AI was not determinative of access. The husband had repudiated his parental rights by taking a financial advantage, not maintaining contact and delaying the application for access for almost two years. Further, as the child was settled in a stable, loving situation no rights would accrue to a husband who was not the biological father.

Finally, in *Re F.(M.A.)*[181] the court refused to grant custody to a single homosexual male who was the biological father of an artificially conceived child. The man had contracted with a mother (previously convicted of killing another one of her children) to provide him with a child so he could secure higher welfare payments as a single parent. The court denied his claim and ruled that the contract violated public policy and would not be enforced.

Like heterosexual couples, homosexual couples have also sought to enforce parental obligations regarding artificially conceived children upon the dissolution of their adult unions. However, unlike heterosexual couples, homosexual couples have sought legal recognition during the pendency of their relationships. The first case involving a lesbian couple was *Anderson v. Luoma.*[182] During their decade long relationship, the women had agreed to have two children that were produced by AI and carried by one of them.[183] In court, the mother

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[181](February 25, 1994) Doc. No F03410 (B.C.Prov.Ct.).

[182]This couple was involved in lengthy ongoing litigation involving support and property claims. See (1984), 42 R.F.L. (2d) 444, 14 D.L.R. (4th) 749 (B.C.S.C.); and also (1986), 50 R.F.L. (2d) 127 (B.C.S.C.).

[183]Dr. Korn provided AI services after noting that the couple had a steady four and one half year relationship. He felt that there was no ethical or legal reason to treat them different than heterosexuals.

claimed maintenance for herself and her two children under the *Family Relations Act*.[184] The Court ruled that the mother was not entitled to child support because the statute did not apply to homosexual relationships.[185]

Since *Anderson*, lesbian couples have had greater success in being recognized under family law statutes.[186] In *Re K.*[187] four lesbian couples successfully applied to adopt their respective children. The children were conceived by AI. One member of each couple was a natural parent. All the children were born during the currency of the respective relationships. All of the couples shared in the care of the children. The Court granted the adoptions based on the children's best interests. The judge ruled that the requirement in the *Child and Family Services Act*[188] that spouses be of the opposite sex in order to apply to adopt children was unconstitutional. The statute permitted adoption by heterosexual couples and by single people regardless of orientation. The Court ruled that the law denied gay and lesbian couples the

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[184]R.S.B.C. 1979, c.121. In stark contrast to decisions made in the late 1990s discussed elsewhere in this chapter, the Court summarily dismissed the claim that exclusions based upon sexual orientation offended the *Charter* with one sentence: "The answer is found in s.1" at 142. This law was subsequently changed to include homosexual couples: see *Family Relations Act*, R.S.B.C. 1996, c.128 where spouse includes people of the same gender living in marriage-like relationships for two years or more.

[185]She also claimed an interest based in contract. The court ruled that the common law was of no assistance, as there was no contract between the parties about support, specific performance could not be ordered. Finally, as the children were not in danger, the Court would not exercise *parens patraie* jurisdiction to order support. Ultimately, her interest in some of the disputed property owned by her partner was recognized.

[186]See for example *M. v. H.* (1996), 31 O.R. (3d) 417 (Ont. C.A.) where a majority ruled that the same legislative system should govern dissolution of intimate homosexual and heterosexual relationships. The majority of the Ontario Court of Appeal ruled that the exclusion of same-sex couples from the *Family Law Act* was irrational and unconstitutional. They determined that marriage was neither fair nor effective as the "exclusive marker" of intimate, economically interdependent relationships which require legislated rules for dispute resolution upon breakdown. Note that an appeal has been heard by the Supreme Court of Canada and is on reserve.

[187](1995), 23 O.R. (3d) 679; 31 C.R.R. (2d) 151, 15 R.F.L. (4th) 129 (Ont Prov. Div.).

[188]*Child and Family Services Act*, R.S.O. 1990, c. C.11, s. 146(4)(b) limited joint adoptions to "spouses"which was defined in s. 136(1) by reference to human rights legislation and was limited to heterosexual partnerships.

right to jointly adopt children based on the analogous ground of sexual orientation and that the discrimination could not be justified under s.1. The objective of the act was undeniably substantial: to promote the best interests, protection and well-being of children by ensuring that they would be cared for, raised and nurtured in a stable, secure, loving and committed family environment, legalized by an adoption order. However, the Court found no rational connection between this goal and the exclusion of homosexual couples:

> there is no cogent evidence that homosexual couples are unable to provide the very type of family environment that the legislation attempts to foster, protect and encourage.
>
> There is no evidence at all that families in which both parents are of the same sex are any more unstable or dysfunctional than families with heterosexual parents. There is no evidence that children raised by homosexual parents are any more likely to develop gender roles or identities inconsistent with their biological sex than children raised by heterosexual parents. There is no evidence at all that children raised by homosexual parents will be significantly any different from children raised by heterosexual parents in all areas of their psychological development.
>
> There is also no evidence that children raised by homosexual parents will be exposed to any greater degree of social stigma than children of heterosexual parents are exposed because of race or any number of other characteristics .... There is, in short, no evidence that families with heterosexual parents are better able to meet the physical, psychological, emotional or intellectual needs of children than families with homosexual parents.[189]

The Court found that there were less restrictive means to meet the goals of the law and therefore modified the statutory definition to include couples of the same or opposite sex living in a conjugal relationship outside marriage.[190]

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[189] *Re K, supra* note 187 at 707-708. The judge also believed that in the event of a break-up, they would be liable to contribute financially to the support of the respective children under the *Family Law Act*.

[190] *Re. K.* was followed in *Re C.E.G. (No. 2) an adoption order under Part VII of the Child and Family Services Act, R.S.O. 1990, c. C-11*, [1995] O.J. No. 4073 (Ont. C t. J. (Gen. Div. Fam. Ct.)) where another judge of the same court ruled that the definition of "spouse" should be modified to allow lesbians in spousal relationships to jointly adopt children born to one of them as a result of AI.

The best interests of the child also governed two custody cases involving surrogacy arrangements. Both cases involved less than idyllic situations. In *Re an Application for the Adoption of a Child, Ontario Birth Registration Number 88-05-045846,*[191] the Ontario Family Court validated an adoption proceeding to give effect to a surrogacy agreement. In this case proposed parents, Mr. and Mrs. X, maintained a common law relationship. Mrs. X could not conceive due to a prior hysterectomy. After all parties received legal advice, Mrs. X's daughter from a prior marriage agreed to be the surrogate for her mother and her mother's future husband (Mr. X had agreed to marry Mrs. X if a pregnancy were to occur). The daughter conceived through AI using the sperm of Mr. X. Two months after conception, Mr. and Mrs. X were married. The daughter lived with Mr. X (now her stepfather) and her mother, Mrs. X, until some time after the birth of the baby. All parties consented to the adoption. In deciding the case, the Court stressed that the best interests of the baby, rather than the agreement should prevail. The judge emphasized that his ruling would address the emotional stress and confusion caused by the fact that the child was her own aunt and that her family members played dual roles. The judge first ruled that the crime of incest did not apply because there was no blood relationship between the biological father and his surrogate step daughter nor had the crime of giving or receiving a payment of reward for adoption or consent to adoption occurred. The judge held that the mother was not coerced and noted that she had received independent legal advice in advance. While the marriage was conditional upon pregnancy, it was not a reward for the surrogate mother who had sixteen months to change her mind about the adoption. The judge noted that legislation could outlaw many

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[191] *Re an Adoption Order Under Part VII of the Child and Family Services Act 1984, S.O. 1984, c.55,* [1990] O.J. No. 608 (Ont. Prov. Ct. Fam. Div.), (QL).

surrogate agreements.[192] Also, he noted that as the mother no longer lived with Mr. X and Mrs. X, the child should not experience confusion. Accordingly, to satisfy the child's best interests, the court ordered the adoption.

By contrast, the Court returned custody to the surrogate mother in *H. (W.) v. P(W.L.)*[193] In this case a 22 year old woman had sex with her mother's new husband, a man in his late 60s, in order to produce a child for the man and her mother.[194] The father had agreed to support the adult daughter for three years. The father exercised control over the baby from its birth. He would not allow the adult daughter unsupervised access to the child. While the parties had originally planned for the adult daughter to consent to an adoption, the adult daughter later reneged and sought custody while the baby was in the interim custody of the natural father and grandmother. After marvelling that the parties did not seem aware of the social stigma attached to the situation and that not one of them had considered how it would be explained to the child, the Court ignored the agreement and awarded custody to the adult daughter based upon the best interests of the baby. In this judgement, the Court noted that the parties had agreed to let the child's best interests govern and they were not seeking to enforce the preconception agreement. The Court cited the RCNRT as support for the position that surrogacy contracts offend public policy in any event.[195]

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[192]He described two earlier cases where adoptions involving remuneration were validated.

[193](1997), 28 R.F.L. (4th) 344 (N.B.Q.B.).

[194]While AI was considered, it was quickly discarded by the father who later sought to maintain a sexual relationship with his step-daughter.

[195]The judge quotes from Proceed with Care, supra note 44 at 666:

> .. There is certainly a body of legal opinion that states that legitimizing preconception arrangements would be inconsistent with existing family law principles. This is because a

2. Personal Injury Cases: Compensation for the Future Cost of Assisted Reproduction

Canadian courts have awarded damages to cover the cost of ARTs when such services are necessary due to personal injuries. These cases recognize that assisted reproduction is a legitimate means of mitigation and that the procedures will involve costs not covered by the provincial health insurance programs.

In *Garat v. Chaisson*[196] the British Columbia Supreme Court allowed an award of $25,500 for procreative assistance based on testimony that the plaintiff was in a serious relationship and that he planned to have two or three children within two years or so. The Court included a 75% discount for contingencies and based the award on the presumption that the plaintiff would have two children and the evidence that AI would cost $9,000 per birth and that IVF would cost $ 15,000 per birth. Similarly in *Ryocroft v. Kyte*[197] a single, unattached 25 year old male plaintiff was awarded more than $19,000 to cover the cost of fertility evaluation and AI and IVF treatments to create two children.[198] The judge was persuaded that the plaintiff had proven a real and substantial risk of a future pecuniary loss for which he should be

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contract that provides in advance for handing over a child at birth would be at odds with fundamental principles of family law - that custody must be determined according to the best interests of the child and that parental authority and obligations cannot legally be "contracted away" in anticipation. Adults cannot simply transfer custody of a child at their whim; the child's best interests must guide decisions and actions in this respect.

[196][1993] B.C.J. No 1588 (B.C.S.C.) July 2, 1993 (QL).

[197][1999] O.J. No 296 (Ont. C.J. (Gen. Div.)).

[198]The total costs for a three phase fertility treatment plan and child care were reduced by 30% to account for three contingencies that the plaintiff may never marry due to emotional problems, that treatment might not be successful and that he might have only one child.

compensated despite evidence that the accident had created psycho-emotional problems which directly interfered with his personal relationships and that in the six years since the accident he had been involved in two unsuccessful relationships. By contrast in *Bains. v. Sandhu,*[199] the Court did not allow recovery for the cost of ARTs, ruling that the claim was too speculative given that the chances of success for the plaintiff could not be estimated because of the nature of his injuries and because the timing and potential cost was uncertain. Finally, in *Moore v. Cooper Canada Ltd,*[200] the Ontario High Court of Justice awarded damages of $1,000 (a sum agreed to by the parties at trial) for the extraordinary cost of AI to a plaintiff injured during a hockey game.

Several cases have recognized the significance of fertility by ordering compensation for the loss of the chance for a child of one's own occasioned by nonconsensual sterilization, accident, iatrogenic injury or otherwise.[201] The importance of the ability to bear children was addressed in *Kelly v. Lundgard.*[202] The plaintiff was injured in an accident which required life-saving surgery. One of the grave risks of the surgery and of the plaintiff's situation was infertility. However, her doctors failed to identify possible infertility in the preparation of medical-legal reports used to settle litigation arising out of the original accident and she

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[199][1997] B.C.J. No 943 (BCSC) (QL).

[200][1990] O.J. No. 66 (Ont. S. Ct. - H.C.J.) January 22, 1990. Supplementary reasons released April 2, 1990 (1990) 2 C.C.L.T. (2d) 57.

[201]Awards and circumstances have been varied. See *Muir v. The Queen* (1996), 132 D.L.R. (4th) 695 (Alta. Q.B.): $250,000 general damages for wrongful irreversible surgical sterilization; *Antonopoulos v. Gillespie*, [1992] 21 W.A.C. 161 (B.C.C.A.): $125,000 for serious motor vehicle accident resulting in ruptured uterus still birth and rendering future pregnancy life threatening; *Hagen v. Dalkon Shield Claimants Trust*, [1988] A.J. No. 1171 (Q.B.) denied causation, but quantum set at $70,000 for infertility to wife and $10,000 to former husband.

[202][1996] 8 W.W.R. 108 (Alta. Q.B.), additional reasons (1997), 47 Alta L.R. (3d) 184.

settled her claim for $16,500. Upon discovering that the accident had rendered her infertile, she sued her physicians for negligent misrepresentation. Madame Justice Veit found the physicians negligent for failing to provide this information to the plaintiff.[203] In a separate memorandum of decision Madame Justice Veit awarded $100,000 in damages (the amount the plaintiff should have received in the original lawsuit for the loss of her reproductive capacity).[204] The award was based on the evidence that having a child was extremely important to the plaintiff, central to her perception of herself as a woman and that infertility was a serious deprivation causing substantial pain and suffering. The Court also held that the plaintiff was not required to undergo IVF to mitigate her loss, nor to obtain a second opinion about her condition. This last point was affirmed in *Adam v. Davis*[205] where the plaintiff was awarded $80,000 for wrongful sterilization. The judge refused to accept the argument that a woman should have to undergo further invasive procedures such as IVF to mitigate her loss of reproductive capacity through unwanted surgical intervention.

In *Berezowski-Aitken v. McGregor*,[206] Mrs. Aitken was rendered infertile after a dilatation of the cervix and curettage of the uterus that resulted in a perforated bowel. The physician had negligently advised the plaintiff about the risks and the alternative courses of treatment and had negligently performed the operation. She was awarded $50,000 in nonpecuniary damages

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[203] She held that the informed consent standard of care applied in the preparation of medical-legal reports dealing with prognosis.

[204] *Kelly v. Lundgard*, [1996] A.J. No 672 (Alta. Q.B.).

[205] [1998] O.J. No. 3030 (QL). The plaintiff was not conversant in English and had not understood the permanent nature of the tubal ligation. She was the mother of four children and in accordance with her religious and cultural beliefs had intended to have as many children as physically possible.

[206] (1998), 127 Man R. (2d) 234 (Q.B.).

for the loss of reproductive capacity. She was also compensated for the cost of failed IVF treatments (approximately $17,000) even though she had been advised that the treatments were unlikely to be successful.

In *Lanthier-Rochon v. Sim,*[207] the Court also considered the cost to produce children through IVF. In this case the plaintiff sued the physician who had performed a tubal ligation for her. She claimed he had assured her that the procedure was easily reversible. The Judge dismissed her claim, but assessed damages in any event at $15,000 for three cycles of IVF treatment.

3. Medical Practice Cases: Standard of Care and Characterization

The most well known and frequently cited Canadian case involving NRTs is *terNeuzen v. Korn.*[208] Ms. terNeuzen sued Dr. Korn in negligence and contract after she contracted AIDS as a result of participating in his AI program. Dr. Korn provided AI services to her for four years. She was infected with HIV from contaminated sperm in January, 1985. Dr. Korn did not warn her that she might contract HIV. The doctor used fresh semen and he did not screen it for HIV at the time of infection. He screened donors by personal interview. Dr Korn rejected homosexual donors on the basis that their sexual practices could result in the transmission of sexually transmitted diseases ("STDs"). The infected donor originally told Dr. Korn that he was heterosexual and admitted to being bisexual only after the infection had occurred. In mid 1985, upon becoming aware of media reports of the infection of four

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[207] [1996] OJ. No. 4449 (Ont. C.J. (Gen Div.)) (QL).

[208] [1995] 10 W.W.R. 1 (S.C.C.). The majority decision was given by Mr. Justice Sopinka with all judges in concurrence except Madame Justice L'heureux Dube who dissented on the unrelated tort law point concerning whether a trial judge ought to instruct the jury about the common law limit on nonpecuniary damages.

Australian women, Dr. Korn immediately discontinued his AI program.

A jury awarded Ms. terNeuzen $460,000 in general nonpecuniary damages, an amount far greater than the permissible limit established by the Supreme Court of Canada. The Court of Appeal overturned the decision and ordered a new trial on certain limited issues. The Supreme Court of Canada affirmed the appeal decision and ordered a new trial on two issues: negligence on a limited basis, and an assessment of the general damages after receipt of jury instructions about the legal limits on nonpecuniary general damages.[209] The Court affirmed the usual tenets of the patient/physician relationship and the established standards of care: first, physicians have a duty to conduct their practices as a prudent and diligent doctor would in the same circumstances; and second, specialists are held to the higher standard, that of an ordinary specialist.[210] The Court also held that while adherence to common practice will generally exonerate physicians from negligence, the standard practice itself may be negligent if it is so 'fraught with obvious risks' that anyone could find it negligent, even without diagnostic or clinical expertise.[211]

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[209] *Ibid.* at 40.

[210] According to the Court, *ibid* at 14-15:

> It is well settled that physicians have a duty to conduct their practice in accordance with the conduct of a prudent and diligent doctor in the same circumstances. In the case of a specialist, such as a gynaecologist and obstetrician, the doctors' behaviour must be assessed in light of the conduct of other ordinary specialists, who possess a reasonable level of knowledge, competence and skill expected of professionals in Canada, in that field. A specialist, such as the respondent, who holds himself out as possessing a special degree of skill and knowledge, must exercise the degree of skill of an average specialist in his field... It is also particularly important to emphasize, in the context of this case, that the conduct of physicians must be judged in the light of the knowledge that ought to have been reasonably possessed at the time of the alleged act of negligence.

[211] *Ibid* at 17 and at 21 the court further elaborates:

> ...where a procedure involves difficult or uncertain questions of medical treatment or complex, scientific or highly technical matters that are beyond the ordinary experience and understanding of a judge or jury, it will not be open to find a standard medical practice negligent. On the other hand, as an exception to

The Court then turned to the specific tort claim, breaking it into two aspects: breach of duty in failing to be aware of the risk of transmission of HIV through AI; and, breach of duty in failing to adequately screen and follow up on donors to eliminate high risk donors that might infect recipients with STDs. With respect to the first aspect of negligence, the Court held that at the time of infection "it was widely believed that HIV was an STD; however, it was hoped that the atraumatic AI procedure was free of risk."[212] It was not known that HIV could be transmitted by AI until later in 1985.[213] Given the evidence about the state of medical knowledge on this point, the Court concluded that it was not possible for the jury to have found that in 1985 the doctor should have known of the risk of HIV transmission. In any event, the Court ordered a new trial regarding the second aspect of negligence because it was open to the jury to find Dr. Korn negligent for failing to adequately screen and follow up donors to prevent the transmission of STDs generally.[214] In outlining the facts, the Court noted that expert evidence showed that Dr. Korn had conformed to general practices used across Canada, particularly with regard to recruiting and screening donors.[215] However, the Court ruled that there was little evidence about standard practice regarding this second aspect; therefore, the jury could decide whether a standard existed. If the jury decided it did

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> the general rule, if a standard practice fails to adopt obvious and reasonable precautions which are readily apparent to the ordinary finder of fact, then it is no excuse for a practitioner to claim that he or she was merely conforming to such a negligent common practice.

The Court later noted that whether or not a standard practice is negligent is a question of law.

[212] *terNeuzen v. Korn, supra* note 208 at 7.

[213] *terNeuzen v. Korn, supra* note 208 at 8-9.

[214] As HIV infection fell within the risk of STD transmission, the doctor could be liable on this point.

[215] *terNeuzen v. Korn, supra* note 208 at 8.

not exist, they could set an appropriate standard based upon what a prudent and diligent practitioner ought to have done to screen and follow up on donors.[216] The Court also ruled that the new jury could consider whether a prudent physician would have used frozen sperm exclusively.

The Court also rejected the three contractual claims advanced by the plaintiff: an express contractual warranty, a warranty implied under the *Sale of Goods Act* and a warranty implied under common law. The plaintiff first claimed that as the information sheets she received prior to treatment stated that the donor would not be a homosexual or a drug abuser, she could rely on the physician to ensure that the semen was free from HIV contamination. The Court rejected this first claim on the basis that the parties did not intend the information to form the basis of contractual liability; the sheets merely provided information that the plaintiff did not even recall receiving. Second, the Court rejected the notion that the *Sale of Goods Act* applied to the contract because the contract was not "primarily for the purpose of selling goods." Ms. terNeuzen went to Dr. Korn because of his medical expertise. Even though AI is not technically difficult, the contract to provide AI procedures was primarily a contract for medical services. The transaction was not in substance a sale of semen although semen was an important part of the deal. Third, the court refused to imply a common law warranty, regardless of negligence, into the treatment contract. The Court examined the nature of the contract and the relationship of the parties to determine if they intended to imply such a warranty. The Court noted that the usual rationale, that the supplier of goods can seek redress

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[216] *terNeuzen v. Korn, supra* note 208 at 24.

against the manufacturer placing responsibility upon the original wrongdoer, should not apply because:

> biological products such as blood and semen, unlike manufactured products, carry certain inherent risks. In some ways, these substances are inherently dangerous, although they are essential to medical procedures. Whether a doctor is trying to save a patient's life via a blood transfusion, or is simply attempting to a assist a patient to become pregnant by AI, the physician cannot control the safety of these products beyond exhibiting the reasonable care expected of a professional to ensure that the biological substance is free from harmful viruses. By contrast, in the commercial world, the manufacturer has control over the goods. If they cannot be manufactured to be safe, then the products ought to be removed from the market. In medicine blood is essential to a variety of procedures in order to save lives. *While arguable, AI is not in the same category as other lifesaving techniques, it is nonetheless a very important medical procedure. As long as the entire procedure does not amount to an unreasonable risk such that it ought not to be offered at all, the patient is entitled to weigh those risks and elect to proceed.* [217]

The Court concluded, after reviewing American authorities, that public policy suggests that in the context of medical services it is inappropriate to apply a warranty of fitness or of merchantability. "The contract was primarily one for medical services and parties would not have contemplated that the respondent would warrant the success of the procedure nor that the semen would not be contaminated with an STD."[218] Alternatively the Court ruled that if a warranty did apply, it would simply be a promise to exercise diligence and due care in selecting donors and providing services. Finally, the Court determined that the nonpecuniary $100,000 damage limit adjusted for inflation should stand; if the judge felt the jury would make an award exceeding the limit, it would be reasonable to instruct them about the limit.[219]

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[217] *terNeuzen v. Korn, supra* note 208 at 33.[Emphasis added.]

[218] *terNeuzen v. Korn, supra* note 208 at 36.

[219] *terNeuzen v. Korn, supra* note 208 at 38.

While *terNeuzen v. Korn* addressed only tortious and contractual liability, it is an important case which answers many legal issues about the nature of the patient/physician relationship, legal obligations arising from it and the state of professional standards in the mid 1980s. The Court recognized that while not a lifesaving procedure, AI is an important medical service. It confirmed that contracts for assisted reproduction were essentially contracts for medical services and were not subject to unique statutory or implicit warranties about treatment or about the reproductive materials integral to the services. In the absence of express contractual warranties, physicians could only be held to the negligence standard of care in the provision of reproductive services. In addition, it is important to note that the Court explicitly refused to deal with the applicability of strict tortious liability, but they recognized it as an issue with "far-reaching implications for the medical profession and the Canadian system of public health insurance in general."[220]

Three cases involving the interpretation of collective bargaining agreements affirm that time off related to infertility treatments constitute "time off due to illness" and qualify for sick leave entitlements. In *O.P.S.E.U. v. Ontario (Ministry of Health)*[221] the Ontario Court of Appeal ruled that infertility was a serious illness and that IVF procedures are treatments to permit normal bodily functioning. Therefore, the time off to partake in the procedures constituted time lost "due to sickness," a decision otherwise would be patently unreasonable. This same

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[220]*terNeuzen v. Korn, supra* note 208 at 6, the issue had been raised for the first time by an intervenor at the final level of appeal.

[221][1989] O.J. No. 2434 (Ont. S.Ct. H.C.J. Div. Ct. C.A.) (Q.L.).

point was affirmed by two labour boards. [222]

4. Availability and Accessibility Cases

As discussed above, the Ontario courts addressed availability in *Wellesley Central Hospital v. Ontario (Health Services Restructuring Commission).*[223] This case involved an application to quash directions of the Commission which had ordered the closure of one public hospital and the assumption of its services by another. As a consequence of the Catholic health care mission of the new hospital, certain services including AI and IVF involving unmarried recipients would not be allowed. Amongst other issues, the complainants alleged that the constitutional rights of women were infringed as all of the previously provided fertility services would not remain available. The Court rejected the argument that the decision constituted a *Charter* breach, ruling that there was no evidence that the failure to offer abortion and other reproductive services and procedures at the Catholic institution would negatively impact women as several other hospitals and abortion clinics in the catchment area would still provide such services. Further the Court decided that the applicants failed to prove it was probable that the prospective *Charter* violations would in fact occur due to the closure of one institution. This case again shows how it may be difficult to establish that individual policy decisions about the allocation of scarce health care resources which limit access to

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[222]In *Hamilton Civic Hospitals v. O.N.A.*,[1989] O.J. No. 2434. (Ont. S. Ct. H.C. J. Div. Ct. C.A.) (QL) the Board accepted medical evidence that infertility was an illness and described medical treatment to achieve pregnancy through IVF treatment as voluntary action, but also as treatment to restore normal reproductive function. Therefore, time required for recovery from an IVF attempt qualified as sick leave. In *Metropolitan General Hospital v. O.N.A.*(1988), 32 L.A.C. (3d) 284 (Ont.) a labour arbitration board held that an employee was entitled to disability benefits when participation in an IVF program required her to miss work for three weeks. According to the Board, infertility due to a pre-existing medical condition constituted a disease.

[223](1997), 151 D.L.R. (4th) 706 (Ont. Gen. Div. (Div Ct.)).

ARTs are unconstitutional, unless the decision results in the total obliteration of programs for a large and definable patient group.

As discussed above in *Cameron v. Nova Scotia (A.G.),*[224] a couple sought to compel the Nova Scotia Government to cover the cost of ICSI within the provincial health care insurance plan. They advanced two distinct claims: first, a proper interpretation of the regulations required IVF to be covered, and second, the exclusion of IVF and ICSI constituted a breach of s. 15 and s.7 of the *Charter*. Justice Hamilton agreed that the couple had public interest standing sufficient to challenge the law, but ultimately denied all their claims.[225]

The judge first reviewed the health insurance system for hospital services and physicians' fees. Together the relevant laws entitled Nova Scotians to receive insured hospital services and insured medical services as well as certain extra-provincial services. Provincial regulations required reimbursement only of insured services that were "medically required." For many years reimbursement and insurance coverage was set for hospital services by the Department of Health and for medical services by an independent commission. In 1992, the commission was stripped of its functions and both services were dealt with by different parts of the Department of Health. Reimbursement of physicians' fees were prescribed by a tariff of fees

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[224][1999] N.S.J. No. 33 (N.S. S.C.) Feb 5, 1999. The husband was a lawyer and the wife was a physician, a resident in obstetrics and gynaecology. The husband suffered from male factor infertility. The couple had sought ICSI services in Ontario and Alberta at their own personal expense. The plan covered some types of infertility treatments, but IVF was specifically excluded under the provincial plan and under the reciprocal provincial reimbursement agreements.

[225]Standing was granted following the three part test set out in *Canadian Council of Churches v. Canada* (1992), 88 D.L.R. (4th) 193 (S.C.C.): there was a serious issue, the plaintiffs were affected or possessed of a genuine interest in the law, and there was no other reasonable and effective way to bring the issue before the Court.

negotiated by the Department and the Nova Scotia Medical Society. In 1992 the total medical fees reimbursement was capped so that any additions or increases had to be accounted for in other areas. The plan covered some types of infertility treatments, but not others. IVF was never on the tariff and it was specifically excluded from coverage in 1996. In addition, IVF was specifically excluded from coverage under the Interprovincial Reciprocal Billing Arrangements.[226]

The province took the position that the services at issue were not medically required. The applicants argued that the services were medically required and therefore should be covered when accessed out of the Province. The judge empathized with the couple, noting the desire to produce one's own child was both understandable and natural. However, he ruled that while ICSI and IVF were medically indicated, they were not medically required or medically necessary.[227] The judge reasoned (somewhat circuitously) that the procedure was not medically required because physicians had not tried to assert that it was medically required by formally asking to have it added to the tariff. As the procedures were not medically necessary, their exclusion was lawful. The Court found that the Minister had lawfully created the tariffs. The exclusion of IVF was valid and had been properly approved by Cabinet.

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[226]Under these bilateral agreements all provinces, other than Quebec, have agreed to cover the cost of certain procedures provided to their residents in other provinces (usually extra provincial treatments are provided to meet an unexpected need or because a medically required service is unavailable within the home province).

[227]The court noted that no other court had chosen to define the term medically necessary beyond the scope of the facts of any given case and he refused to do so. He gave several reasons for his conclusion with respect to IVF. First he noted that the expert for the plaintiff stated it was difficult to make a strong case that the procedures were medically required as couples faced with severe male infertility have several options: simple acceptance, empiric treatment, donor insemination, IVF with ICSI or adoption. The success rate of the procedure was only 15-20% and it involved maternal risks and added risks of fetal anomaly. He noted that the medical profession had not attempted to have the procedures at issue added to the tariff. He found the extra provincial exclusion of IVF a significant factor.

Further, it was lawful for the government to restructure its health care system and to reassign the functions of the independent reimbursement commission to the Minister of Health.[228] Accordingly the judge dismissed the administrative law claim that the exclusion was unlawful.

The judge then rejected the two constitutional claims. The Court adopted the two step approach propounded in *Vriend v. Alberta*[229] to determine whether or not the exclusion of IVF violated s. 15 of the *Charter* by discriminating unlawfully against infertile couples. He decided that while the exclusion was a law sufficient to attract the *Charter*, the exclusion did not violate s.15. In reaching this conclusion, the Court rejected the plaintiff's characterization of the law as a distinction that denied infertile people comprehensive medical coverage effectively preventing couples with male factor infertility from the opportunity to have children. The Court instead framed the issue as narrowly as possible finding that the distinction was simply a refusal to pay the costs of IVF and ICSI. The judge noted that many other unrelated medical services were not funded and many infertility services were funded. While only infertile couples would seek IVF and ICSI, infertility was simply not the issue. The direct exclusion was based upon the choice of the medical profession not to bring the procedures forward for funding consideration through the usual administrative channels.[230] Because of this holding, the judge did not address whether or not infertility constituted a disability as an impairment of a natural human function similar to impairment of hearing; or,

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[228]In the words of Judge: "This may, or may not, be the best way to administer medicare, but it is the way that the government of the Province has chosen to proceed and it has been accomplished lawfully" at para 127.

[229](1998), 212 A.R. 237 at 287 (S.C.C.).

[230]On one occasion in the early 1990s the Medical Society was asked to add IVF to the fee structure, but the Society did not take the claim forward as the procedure was considered new and experimental.

whether infertile persons otherwise constituted an analogous group who suffer prejudice, social disadvantage and ostracism.

Finally, the Court rejected the allegation that the elimination of the commission breached any s.7 entitlement to life, liberty or security of the person. The Court found "that finding public funding of particular medial services to be considered an element of the right to life, liberty or security of persons would expand the parameters of judicial review, well beyond its present scope."[231] In any event, the plaintiffs still had a means to appeal the exclusion despite the fact that the commission was now defunct, therefore the s.7 claim could not be sustained. In closing the Court cautioned that the judiciary should adopt a deferential stance to the issue of funding specific treatments:

> The Canadian Health Care System remains one of the best in existence, but it is not unlimited.
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> It cannot possibly fund every medical service available and, in fact, now struggles to fund those services traditionally covered.
>
> The policy established by law that controls funding in Nova Scotia, involving as it does, the participation of the government, answerable for how it spends public funds, and the Medical Society best able to determine how limited funds should be used, is a reasonable one....
>
> This action by the plaintiffs, on their own behalf and on behalf of other infertile couples throughout this Province and Canada, is sincere and perhaps even noble, however, the cause of public health insurance coverage for I.V.F. in Nova Scotia at least, is obviously compromised unless it gains Medical Society support.
>
> Courts should take care before interfering with an elected government's allocation of limited public funds for social programs or the medical profession's

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[231] *Cameron, supra* note 224 at para 160.

determination of health priorities.[232]

The reasoning in this case is quite circular. The main justification for exclusion is that doctors did not object to exclusion. The case would have been far more consequential if the Camerons had been able to commandeer support from the medical community. However, this case shows the limits of administrative law principles and sections 15 and 7 of the *Charter* as the foundation for an entitlement to specific ARTs. It also shows the extreme judicial caution typical of cases where the applicant seeks to impose a positive obligation on the elected government to provide and insure a specific service out of the limited public purse. It illustrates the deferential stance that the courts will adopt when the assessment of medical need and the opinions of physicians are at issue.

Another reported Canadian case dealt with access to reproductive services. It also involved Dr. Korn. He had provided services to lesbians until he was involved as an expert witness in a custody and support case between a former patient and her partner.[233] While the names of the parties were protected, his was not. As a result of unwanted publicity associated with his testimony, Dr. Korn subsequently refused to provide assisted reproduction services to lesbians. However, he did provide them with all other services. Pursuant to this policy he refused to provide AI to a lesbian couple, but did refer them to two other physicians. The couple (a doctor and a lawyer) unsuccessfully lodged a complaint with the medical college

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[232]*Cameron, supra* note 224 at para. 166-171.

[233]The case was *Anderson v. Luoma, supra* note 182.

that Dr. Korn's actions were unethical and that he should be disciplined.[234] The couple subsequently filed a complaint against Dr. Korn with the provincial human rights council. The Council designate found that Dr. Korn did not have justification to refuse lesbians because he gave them all other services and he provided AI to single heterosexual women (who like lesbians would not expect to receive spousal support). According to the designate, the doctor's real concern was the fact that he had been publicly exposed as a doctor who had done something wrong. In *Korn v. Potter*[235] Dr. Korn sought judicial review of a decision of a designate of the provincial Human Rights Council that he discriminated against the couple on the basis of sexual orientation. On judicial review, the British Columbia Supreme Court determined that the decision of the designate was not unreasonable. The evidence suggested that Dr. Korn refused to provide services due to the negative public perception of the propriety of providing services to lesbians and due to personal economic consequences, rather than due to concerns about contributing to the birth of children who might be financially disadvantaged because of the failure of the law to bring such relationships into the family law regime.[236]

5. Conclusion on Canadian Cases

The Canadian case law is quite sparse in comparison to other jurisdictions. While it is useful to examine the types of issues that have promoted litigation to assess the suitability of various

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[234]The responsible disciplinary council determined he was not guilty because the couple's need was not urgent in the circumstances and he had the right to refuse patients. The council was unable to conclude that the doctor did not have *bona fide* concerns about the impact on his practice and his ability to serve other patients.

[235](1996), 134 D.L.R. (4th) 437 (B.C.S.C), 22 B.C.L.R. (3d) 163; aff'ing (1995), 23 C.H.R.R. D/319.

[236]*Ibid.* at 450-451.

regulatory models, the dearth of Canadian cases makes analysis difficult. The lack of litigation could suggest that the current policy of professional deference and residual judicial involvement is suitable; that Canadians are less litigious; or, that it is simply a matter of time before these cases arise in Canada. However cases such as *terNeuzen* reveal that medical standards (at least those in place in the mid 1980s) may be sorely inadequate.[237]

Regardless of the existence of legislation specific to ARTs, the Canadian Courts appear very able to deal with issues considered in Canadian law reform reports to be most in need of statutory clarification: professional liability issues and residual family law issues.[238] The Courts also appear prepared to accept that assisted reproductions, at least in the context of curing infertility, is an important medical service. These cases demonstrate the importance of reproduction and how it can lead to disputes fundamental enough to break longstanding relationships. It is clear the usual standards of care will apply to ART treatments. Further ARTs must be provided in a manner consistent with the *Charter*. The cases also suggest that the judiciary will be quite reluctant to force governments to ensure a full range of treatment options within the public health insurance plans. As the existing cases lack consistency and as many key issues such as the control over gametes and embryos have not been addressed, the law may serve an important function of defining acceptable moral limits and increasing certainty for participants.

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[237]After extensive review, the RCNRT also concluded that the current situation is inadequate and results in uneven, unsafe and even unethical practices see chapter 4, *infra*.

[238]See chapter 4, below.

CHAPTER FOUR: *Assisted Reproduction and Canadian Law Reform*

Interest in medically assisted procreation and legal reform has been high around the world. Canada has been no exception to this trend. This chapter reviews the main Canadian law reform projects dealing with ARTs.[1]

A. Provincial Inquiries:

1. British Columbia Royal Commission on Family and Children's Law, Artificial Insemination (1975)[2]

This brief report formed part of an extensive study of family relationships, children, the justice of existing laws and the need for legal revisions. It dealt solely with AI from a family law perspective and addressed only a few of the key issues. The recommendations were quite general and little supporting discussion was provided. The Commission did not question the morality or efficacy of AI, accepting it as an ethical and established medical practice from the outset.[3] Throughout the report, the Commission relied heavily on individual judgement and professional standards, rather than statutes or regulations, to guide individual treatment decisions. The Commission concluded that law should neither prohibit, nor promote AI: instead legislation should be a remedial tool to clarify a few points, allocate risk and resolve

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[1]One Canadian report, *Quebec Comitee de Travail Sur les Nouvelle Technologies de Reproduction Humaine, Rapport* (Quebec: Barreau, 1988) has been omitted as an English translation was unavailable.

[2]British Columbia, Royal Commission on Family and Children's Law, *Ninth Report of the Royal Commission on Family and Children Law: Artificial Insemination* (Vancouver: The Commission, 1975) (authorized by O.C. No. 4043 December 6, 1973) [hereafter *Artificial Insemination (B.C.)*].

[3]The Commission did briefly mention two key ethical issues: whether policy and legislation should be formulated and if so upon what basis. While they conclude it is possible to arrive at some broad yet contentious ethical norms upon which to base legislation, the Commissioners did not elaborate about these norms.

legal disputes amongst the interested parties.[4] According to the Commission:

> the practice of AID is completely optional, the law should not have to serve as a moral justification for it. We do not think that any individual has unfettered right to AID. We take the view that guidelines should be laid down to govern AID in order to enable physicians to provide AID in a rational and socially acceptable way.[5]

The Commission recommended novel statutory provisions clarifying doctors' responsibilities to negate the possibility that physicians providing AI could be held to an unreasonably high standard of care.[6] Under the proposed act, physicians would be required to meet the standard of care generally applicable to medical treatments. They would not be strictly liable in tort or contract (under an implied warranty) for any adverse results or birth defects. If physicians followed all appropriate practical safeguards and exercised care in selecting, processing and administering seminal fluid, then they would not be responsible for complications in pregnancy or birth defects. By statute, any failure to fully disclose AI related risks would constitute negligence.[7]

Despite earlier comments about the limited function of law, the Commission proposed a highly regulated system (similar to the adoption regime) to control access to AI. The highly intrusive proposals employed both professional standards and administrative law mechanisms. Physicians would control access based upon their professional judgement and standard

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[4]These remedial enactments would govern litigation related to malpractice claims; claims that AI constituted adultery; and, claims of estate dilution caused by AI.

[5]*Artificial Insemination (B.C.), supra* note 2 at 8.

[6]The Commissioners expressed concern that physicians might become insurers for perfect outcomes, or held to a higher standard because AI did not have a curative purpose. Further, as it would be unlikely to absolve the physician from liability to the resultant child, the Commission might be exposed to liability for wrongful birth.

[7]*Artificial Insemination (B.C.), supra* note 2 at 25.

guidelines approved by the provincial Medical College and other government agencies. Physicians would assess the physical and mental health of potential recipients and their ability to nurture and meet the needs of children. The chance for a child would only be available to individuals judged to be "suitable parents for adoption." As with adoption, marital status would not be determinative. If refused treatment, a woman could seek out another doctor or appeal to a multi-disciplinary tribunal empowered to review her request and to make recommendations for or against her to the College of Physicians and Surgeons or to the refusing physician. Despite the appeal process, individual physicians would always retain the right to refuse a request for AI.

Approved patients and their spouses would sign prescribed consent forms[8] which specifically absolved physicians and other providers from responsibility for the physical and mental characteristics of any child produced as a result of the AI. The execution of these forms would trigger legal paternity. To further ensure parental responsibility and to preserve confidentiality, the Commission proposed amendments to the provincial vital statistics laws to permit AI children to be inconspicuously registered as children of the intended father.

Consistent with the general view that AI should be kept secret (subject to parental discretion), the Commission felt donor sperm should be selected based upon the visible characteristics and blood types of the parents to avoid the embarrassment of "unintended exposure" of the child's

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[8]Sample consent forms which contemplated married couples were appended to the report. The Commission acknowledged that donors would remain anonymous and that religion would not be a selection criterion. Further, recipients would agree to be totally responsible for the child and to absolve the physician and others from liability for any physical or mental characteristic of the child produced by AI.

origin. Further, donors would remain completely anonymous and unconnected to recipient families. However, physicians would be legally obliged to maintain a body of confidential information for the government about research, quality control and the health of the resulting children. The Commission also recommended that potential donors and their spouses receive counselling. Prior to providing semen, donors would also be required to execute written consent forms documenting this counselling and absolving doctors of any legal liability. Donors would be screened for infections, diseases and genetic abnormalities through detailed, verifiable family histories, physical exams, chromosome studies and metabolic studies. Pregnancies per donor would be arbitrarily limited to six to preclude the production of a large number of children with the same abnormalities. Donors would be reimbursed for time, expenses and loss of revenue only.

Despite determining that AI was not life saving or even disease related, the Commission concluded it should be made available for free within the standard medical plan.[9] The Commission opposed private corporate involvement and recommended the establishment of public sperm banks and the exclusion of private banks unless they were subject to strict governmental surveillance. Finally, the Commission urged the Federal government to regulate sperm banking and the collection, processing, distribution and documentation of services under a system similar to the food and drug regime.[10]

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[9] *Artificial Insemination (B.C.), supra* note 2 at 13.

[10] *Artificial Insemination (B.C.), supra* note 2 at 33.

2. Law Reform Commission of Saskatchewan, Tentative Proposals for a Human Artificial Insemination Act (1981)[11]

Six years later, the Law Reform Commission of Saskatchewan (the "LRCS") released a report which also dealt solely with AI. It included proposed legislation. The LRCS was particularly concerned with ensuring that physicians properly screened potential donors and with clarifying the respective responsibilities of genetic and social parents. The Commission noted a lack of relevant statutes or common law precedents, as well as a lack of a consensus in the medical profession with regard to AI transactions. Like many others, the LRCS took the position (without explanation or support) that ARTs were legally unique, stating "it is not particularly helpful to adopt conclusions based on analogy to other types of human relationships, legal structures or medical procedures."[12]

The report narrowly focused on AI provided in the context of heterosexual marriage relationships, specifically the legal responsibilities of physicians, donors, inseminated women and their husbands and children.[13] The LRCS recommended that AI should not constitute adultery.[14] If a husband consented to AI, then the child would become his legal child for all purposes.[15] If a husband did not consent, then the child would have the same status as any

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[11]Law Reform Commission of Saskatchewan, *Tentative Proposals for a Human Artificial Insemination Act* (Saskatoon: the Commission, 1981) [Hereafter, *Tentative Proposals (Sask.)*].

[12]*Tentative Proposals (Sask.), supra* note 11 at p 2.

[13]One Commissioner dissented, arguing that AI should only be provided by medical practitioners if the woman was legally married and living with the husband who consented in writing because such social policy should not be left to doctors.

[14]*Tentative Proposals (Sask.), supra* note 11 at 2-5 - 2-7 and *Tentative Proposed Act*, s. 18.

[15]*Tentative Proposed Act*, s.19.

other child produced by a married woman and another individual.[16] Anonymous donors would have no rights or responsibilities unless they provided semen despite knowledge that either the husband did not consent or the recipient was a single woman.[17] Donors were legally obliged to disclose diseases, genetic defects and medical conditions of themselves and of their blood relatives.[18]

The LRCS clearly preferred professional self-regulation to external legislative interference. The Commission endorsed legislation merely as an interim measure to govern certain essential issues such as donor screening since at the time professional standards were inadequate or nonexistent.[19] The LRCS concluded that the particulars of investigation, beyond minimal medical screening, were best left to be determined by the patient and the physician free of regulatory interference.[20] The LRCS did endorse some measure of patient autonomy noting that women should be free to select specific donors. They argued that physicians should not refuse to provide AI from a selected donor as the same result could be achieved through sexual intercourse or home insemination. The proposed statute restricted AI practice to

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[16]*Tentative Proposed Act*, s. 21.

[17]*Tentative Proposed Act*, s.22 provided that knowledgeable donors could not contract out of maintenance obligations.

[18]*Tentative Proposed Act*, s. 5.

[19] See *Tentative Proposals (Sask.)*, *supra* note 11 at 1-6 - 1-10. The *Tentative Proposed Act* provides in s.8 that common law rights not expressly altered by the act are preserved.

[20]It was felt that regulation should not create external controls upon decisions between husband and wife. These should be "a matter of choice for the couple, made in consultation with a physician" *Tentative Proposals (Sask.)*, *supra* note 11 at 2-18.

licensed physicians[21] and obliged physicians to screen and investigate donors[22] and to maintain records.[23]

The LRCS outlined five potential sources of tortious liability applicable to professionals providing AI: failing to properly investigate and screen nonspousal donors; failing to detect a medical reason against pregnancy; making fraudulent or negligent misrepresentations about pregnancy-associated risks or the risks of producing a defective child; and, failing to advise the recipient about the risks of pregnancy or of a defective child. According to the LRCS, existing tortious and contractual law principles of general application would adequately protect the physician and the recipient of AI, subject to a few statutory alterations. First, the law would preclude implied warranties about semen concerning defects that could not have been discovered upon reasonable investigation and screening.[24] Second, contractual waivers of liability for negligence would have no legal effect. Also physicians would be required to produce prescribed records showing that their investigations had been reasonable, or that the injury was unrelated to their failures.[25] Third, the LRCS recommended that children born of donated sperm should have negligence claims for specific damages suffered rather than claims for damages to place them in the same position as children born of AI without negligence.[26]

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[21]*Tentative Proposed Act*, s.3.

[22]*Tentative Proposed Act*, s.4.

[23]*Tentative Proposed Act*, s.6. The LRCS recommended that no laws be adopted forcing physicians to disclose donor's genetic defects revealed after AI has occurred.

[24]The novel negligence rules and evidentiary burdens are found in ss.14-17 of the *Tentative Proposed Act*.

[25]*Tentative Proposals (Sask.)*, *supra* note 11 2-24 - 2-25.

[26]The child's unique right of action is in s.12 of the *Tentative Proposed Act*.

To ensure both a steady supply of sperm and that the parents and children would remain free from donor interference, the LRCS suggested changes to evidentiary law principles to protect donor identity. They concluded that it was more important to protect donor anonymity than to assist the offspring to pursue subsequent negligence claims. This conclusion was interesting as it explicitly compromised the best interests of existing children in need based upon the interests of adult participants. The LRCS also endorsed a novel statutory tort to compensate for pain caused by the disclosure of donor identity. Wide powers to enact regulatory details about investigation and screening standards, the form and content of records and any other matters were delegated to the Lieutenant Governor in Council. Any violation of the act constituted a summary offence.[27]

The Tentative Proposals were released for public comment in 1981.[28] Six years later the LRCS released *Final Proposals for a Human Artificial Insemination Act.* Both the final report and the act were substantially abbreviated. The report was expressly restricted to heterologous AI used by married couples to overcome male infertility or genetic disorder.[29] The nine-page report was silent on many previously addressed issues. The five sections of the proposed single-page act contained no indication of its purpose or goals. All provisions about revising contract and tort principles; imposing specific duties and liabilities upon physicians

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[27]*Tentative Proposed Act*, s.24.

[28]The preliminary report and draft act were prepared by research staff and tentatively adopted by the Commissioners. All three Commissioners were lawyers. A research director, three legal researches and one physician in the role of a special medical consultant were also involved.

[29]Other techniques were known and being written about at this time. The Ontario Law Reform Commission Report, *infra* released in 1985 dealt with IVF, surrogacy and other situations involving *ex corporal* embryos.

and all references to known donors and to unmarried women were dropped. The LRCS determined that issues it earlier proposed to address by statute (such as screening) were best left entirely to the medical profession and to incremental development under the common law by the application of legal principles of general application and by analogy. The only urgent issue warranting statutory intervention was ensuring the status of the children with respect to parental support and inheritance rights. The existing common law was not "able to evolve a satisfactory approach to the question of the status of a child born as the result of A.I.D. without legislative intervention"[30] because it lacked an appropriate analogy for the situation. Accordingly s.3 of the proposed act provided that if the husband of a married woman consented in writing to AI, he would be deemed to be the father for all purposes. Conversely, anonymous donors were deemed not to be fathers for any purpose. Section 5 protected donor anonymity by prohibiting disclosure of identifying information. There were no sanctions for violations of the statute. In short, the LRCS made a large philosophical change and adopted a noninterventionist policy which left all treatment issues to the discretion of physicians within the self-regulating professional model.

3. Ontario Law Reform Commission: Report on Human Artificial Reproduction and Related Matters (1985)[31]

While the LRCS was preparing its final report, the Ontario Law Reform Commission ("OLRC") released *Report on Human Artificial Reproduction and Related Matters*.

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[30]Law Reform Commission of Saskatchewan, *Proposals for a Human Artificial Insemination Act*, (Saskatoon: The Commission, 1987) at 1.

[31]Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters*, (Toronto: Ministry of the Attorney General, 1985) [Hereafter *Related Matters (Ont.)*].

Considerably broader and more extensive than its Saskatchewan counterpart, this report covered a variety of services including AI, IVF and surrogacy. It also considered alternate philosophical policies and the reform initiatives of other jurisdictions.[32] Yet the report was also somewhat narrow, restricted for the most part to specified issues raised by persons seeking assisted conception due to "medical need" or "genetic impairment."[33] This limit allowed the OLRC to avoid some difficult issues associated with access, supply and social situations.[34] The report followed a medical architecture outlining the causes of infertility and the current technological solutions.

The OLRC then turned to the existing Canadian laws affecting ARTs, concluding that they

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[32]The report frequently referenced foreign alternatives and reviewed proposed reforms in the United Kingdom, Australia and the United States see *Related Matters (Ont.), supra* note 31 at 295-389. See also at 130-137 for a summary of foreign reform efforts which noted wide variations in reports, the tendency to focus upon AI, the consensus that something must guide scientific advances in this area and great discomfort with surrogacy.

[33]The OLRC's terms of reference consisted of 10 specific legal issues set out by the Attorney General.

1. The legal status and rights of the child and the safeguards to protect the best interests of the child.
2. The legal rights and duties of each biological parent.
3. The legal rights and duties of the spouse, if any, of each biological parent.
4. The nature and enforceability of agreements relating to AI and related practices.
5. The nature and enforceability of agreements respecting custody of the child.
6. The legal rights and liabilities of medical and other personnel involved in performing AI and other related practices.
7. The legal procedures for establishing and recognizing the biological parentage of children born as a result of these practices.
8. The applicability of present custody and adoption laws in such cases.
9. The availability of information to identify the child and the parties involved.
10. Such medical and related evidence as may have a bearing on the legal issues raised in these cases.

[34]*Related Matters (Ont.), supra* note 31 at 9-10 .

> we do not address the situation of women who prefer not to interrupt their careers with a pregnancy, nor that of individuals who would like to become parents, but who lack partners, for natural reproduction, and who do not wish to find one for the exclusive purpose of having sexual intercourse in order to produce a child. In our view, these reasons for choosing an artificial conception technology reflect personal choices that bear no relation to the issue of medical need with which we are here concerned. Whether such motives deserve recognition is an entirely different matter, which is intimately related to questions concerning the availability of the various technologies and is better left to be addressed in that context.

either ignored participants' needs or addressed them coincidentally.[35] The OLRC considered two policy models: "private ordering" and "state regulation." Under the private ordering approach, law is constructed to give maximum effect to the intentions of the individual parties by allowing unrestricted access to any procedures for any price. Private market forces and existing legal principles guide the provision of reproductive services and the resolution of disputes. By contrast, under the state regulation approach, free choice is limited by laws which establish mandatory normative spheres or standards of conduct. The OLRC noted that while natural conception and child rearing was traditionally subject to a private ordering approach (absent extreme need for intervention), adoption was a highly regulated field in which potential parents were intensely scrutinized (unless the process involved a partial genetic bond, i.e., adoption by a step parent). Ultimately, the OLRC did not subscribe completely to either theory arguing that a macroscopic approach may not be appropriate to deal with individual facets of ARTs.[36] In the words of the Commission:

> we regard the general issue as being whether the law should facilitate the exercise of free choice by participants in these procedures or should intervene, through the imposition of normative standards, to subordinate individual choice to other values important to the community. In the result, we do not select either of these paradigmatic approaches as being generally applicable to all the technologies in question, nor indeed to any one of them. We believe that the variety and complexity of the numerous issues raised by these technologies does not permit an *a priori* uniform response, but demands a flexible approach that addresses each issue individually.[37]

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[35]In the words of the Commission *Related Matters (Ont.), supra* note 31 at 118:

> The present legal regime, then, even in the context of artificial conception, may in one sense be characterized as a mix of unconscious or indirect state regulation and private ordering, although, to meet the wishes of the parties in many cases, there must be reliance on legal presumptions fashioned for different times and purposes, rather than on the truth.

[36]*Related Matters (Ont.), supra* note 31 at 107.

[37]*Related Matters (Ont.), supra* note 31 at 7.

Further, the OLRC noted that while there was no community consensus on all issues, the public did support **some** degree of intervention:[38]

> the reasons advanced above for endorsing a type of state regulation approach in the area of artificial conception are founded ultimately on a wider, community interest. Society clearly has an interest in protecting its constituent members - and particularly those, such as children, who can least protect themselves - for , in so doing, it essentially ensures its own well being. We believe that artificial reproduction has a unique, public dimension that necessitates the kind of state intervention that we recommend in this Report.

To find the optimal point on the regulatory spectrum, the OLRC followed the guiding principle that intervention was not warranted unless the public interest was likely to be threatened or frustrated by the absence of some regulation. The OLRC failed to clearly articulate the precise meaning of public interest. The need for law to serve the best interests of potential children was emphasized throughout.[39] The OLRC placed high value on the professional judgement of physicians with little discussion of the conflicts inherent in this professional role or of the rights of patients.

Generally, the OLRC was prepared to leave the regulation of ARTs to the preexisting professional safeguards and individual consciences. However, with respect to certain issues, the OLRC considered internal mechanisms inadequate to protect the public interest. The Commission recommended that regulatory power to enact specific rules be delegated to

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[38]*Related Matters (Ont.), supra* note 31 at 121. The OLRC specified that the parties' wishes, especially the intended parents, was only one factor to consider in policy development and true private ordering would not be acceptable.

[39]Interestingly, the OLRC was opposed to wrongful life claims but was prepared to create barriers to access to prevent children from being born into "unsuitable" environments.

existing provincial agencies.[40] After reviewing competing arguments about artificial conception, the OLRC concluded that ARTs were morally appropriate means to combat the increasing prevalent medical affliction of infertility.[41] The OLRC concluded that the provision of ARTs should be classified legally as 'practice of medicine' to be supplied only under the supervision of physicians. This professional monopoly, while creating some restrictions upon access and liberty, would ensure quality and therefore promote public health and welfare because doctors were the professionals best equipped to prevent, detect and treat health hazards for the patients and their children.[42] This classification would also bring the provision of ARTs within the current self-disciplinary system within which standards of qualification, practice and professional ethics could be developed, monitored and reviewed in a manner consistent with the public interest. This regulatory model would also ensure some measure of accountability as the Provincial College was indirectly responsible to the public, the Lieutenant Governor in Council and the Minister.[43]

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[40]Such as the College of Physicians and Surgeons, the Department of Health, the Department of Community and Social Services, the Lieutenant Governor in Council and the Minister of Health.

[41]The OLRC rejected the argument that the separation of intercourse from procreation could either violate the sanctity of marriage or destroy the family unit.

[42]For discussion of safety factors see *Related Matters (Ont.), supra* note 31 at 35-36.

[43]In the words of the OLRC, *Related Matters (Ont.), supra* note 31 at 153:

> ...the commission fully supports the attempt to promote community health standards and to protect recipients and children involved in artificial conception. However, not every measure of control is necessarily in the public interest; there must be a perceived goal that cannot otherwise be realized without such intervention. We do not believe that a further overlay of licensing, involving a new or expanded bureaucratic involvement in health care, is required to protect the community or its constituents ...the nature and scope of the *Health Disciplines Act* and the regulations made under it, the monitoring, disciplinary control, and public accountability of the College of Physicians and Surgeons of Ontario, the jurisdiction of the College to establish binding rules or standards in respect of artificial conception practices, the ultimate control by the Ministry of Health, and the professional expertise and ethics of the medical profession itself, offer, along with the further proposals... a sufficient measure of supervision and regulation of artificial conception services...

Specific proposals for reform were split into three categories, each successively subject to more regulatory intervention: issues raised by all forms of artificial reproduction; issues raised by the existence of excorporal embryos; and, issues raised by surrogacy.

a. The Provision of Reproductive Services

The OLRC proposed legal clarification regarding eligibility, donor screening, and status of artificially conceived children.[44] The Commission left donation (including selection criteria and frequency of use)[45] to the discretion of individual practitioners, despite the profession's failure to develop formal guidelines and despite the fact that practices across the province varied with respect to selection criteria such as reproductive history, genetic make up, general medical status, and other social psychological and physical characteristics.[46] The OLRC determined that "given the nature of the material donated, donors are significant moral actors in a critically important facet of human life"who must provide full and informed consent. [47] Donors would be entitled to restrict subsequent uses and to revoke consent unless the

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[44]The OLRC concluded that in law AI and IVF should be treated the same because they ultimately raise the same legal issues, see *Related Matters (Ont.), supra* note 31, Proposal 5.

[45]The Commission determined that problems of overuse were unlikely and that the paperwork would not be warranted, *Related Matters (Ont.), supra* note 31 at 170.

[46]The OLRC conducted a survey to determine the practical limits on access. They found less access for single women, ambivalent couples, couples lacking financial resources and couples with a mentally retarded partner. Other recipient screening factors included consent of husband, divorce, and sexual orientation of woman. Few practitioners relied on a home study or psychiatric assessment. As for donors there was great variation in screening for blood group and type, diseases, or genetic problems.

The OLRC recommended against a full codification because it would be impossible or impractical to specify in a statute what must constitute a required medical procedure, especially as technology is constantly evolving. Further, the OLRC reasoned that if the code was too detailed then the law itself may chill the development of appropriate medical criteria.

[47] *Related Matters (Ont.), supra* note 31 at 167.

materials had already been used. The majority agreed with the current law that allowed minors to donate sperm, but not ova (unless indirectly obtained during other surgeries).[48] The OLRC did not consider the propriety of harvesting ova from embryos, or of making treatment conditional upon donation. To prevent "unacceptable commercialization" the OLRC endorsed compensation for donor inconvenience, but not payment for gametes. The Commission accepted the use of intermediaries noting that other medical procedures have always been available for cost and frequently for profit.[49] The OLRC did not consider the effects of commercial involvement upon other issues such as access, but did recommend that commercial banks should be publicly accountable under provincial and federal laws.[50]

The OLRC determined that unfettered patient access would not be optimal for children or the public.[51] The OLRC was in favour of restricting access to stable single women and stable men and women in stable marital or nonmarital unions.[52] Access, more specifically stability, was one key matter not amenable to professional discretion alone. Applicants were to be screened in accordance with regulations enacted under the *Health Disciplines Act*.[53] Potential patients

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[48]The OLRC reasoned that this would prevent wastage. The lone dissenting Commissioner argued ova could be donated directly by minor females if a judge agreed.

[49]The OLRC argued that intermediaries have better screening processes and provide more detailed information. Given that they could assure supply and quality it was acceptable to have them pay money for sperm ova and embryos, *Related Matters (Ont.)*, *supra* note 31 at 172.

[50]*Related Matters (Ont.)*, *supra* note 31 at 173.

[51]Interesting since the OLRC effectively legislated these potential persons out of existence and at the same time determined that the laws were to place paramount emphasis upon the interests of these children. However, by requiring that the future child be born into and reared in a satisfactory home environment, they undoubtedly eliminated some adequate and superior homes.

[52]There was no discussion of lesbians making use of ARTs, *Related Matters (Ont.)*, *supra* note 31 at 158.

[53]Recommendation 6, *Related Matters (Ont.)*, *supra* note 31 at 275.

could appeal refusals through existing administrative appeal mechanisms or through judicial review procedures.[54] The OLRC felt that the status and rights of children born through ARTs were of "such fundamental importance to parents, children and third parties that they no longer ought to be left to the uncertainties and vicissitudes of evolutionary legal development."[55] The OLRC recommended the enactment of legislation to explicitly preserve secrecy, regularize the social reality and ensure the children's legal rights as well as their social and psychological stability.[56] Any consenting male husband or partner would be rebuttably deemed to be the legal father for all purposes. Absent spousal consent, children would remain legally fatherless.

Apart from a few minor revisions, provincial laws pertaining to medical records were deemed sufficient.[57] For example, the OLRC recommended a law declaring donors to be patients so the existing confidentiality laws would extend to their files. This was important because linking information would be required to be maintained by statute in case the subsequent children required medical, genetic and heritage information. The linkage would be kept from the parties, but not the physicians. If doctors subsequently became aware of a genetic defect or disease in a donor, they would be under a professional duty to make all reasonable efforts to report all relevant information to any person whose health and welfare may be affected. If

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[54]*Related Matters (Ont.), supra* note 31 at 53-59. This is one of the few comments about patient rights or patient judgement.

[55]*Related Matters (Ont.), supra* note 31 at 103.

[56]*Related Matters (Ont.), supra* note 31 at 78. The OLRC argued that statutory intervention was required because status affects the lot of the child. The law should remove uncertainty and regularize the family relationship.

[57]*Related Matters (Ont.), supra* note 31 at 83.

physicians failed to warn the affected parties then they would be liable under existing civil and professional misconduct laws. However, the law would not create a positive obligation to follow up on all former patients.[58] A majority of the OLRC felt access to information amongst the parties should be left to the judgement of medical practitioners not to the women, spouses, donors or offspring involved.[59]

The OLRC considered other unique sources of civil and criminal liability arising in conjunction with the improper provision of ARTs, but concluded that these issues were more properly considered within the context of tort laws in general.[60] For example, under existing tort laws, the suppliers of gametes and embryos would not be strictly liable for defective gametes and embryos. The OLRC concluded that gamete donors should be responsible for intentionally concealing or misrepresenting relevant facts.[61]

b. Excorporal Embryos

The OLRC made several recommendations on issues raised by the existence of excorporal fertilized ova. First, the OLRC acknowledged the value of embryonic research for increasing success rates and understanding early developmental abnormalities. Then the Commission recognized the general absence of laws or codes respecting the use and destruction of human

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[58]The OLRC did not consider how creating an incentive not to follow up would affect the doctors.

[59]However, the dissenting Commissioner recommended that children, once of age, should have access to non-identifying information and a minority of Commissioners concluded that the donor should have access to non-identifying information about the recipient woman and child.

[60]The Commissioners considered four specific types of tort actions: wrongful conception, wrongful birth, wrongful life and dissatisfied life.

[61]The OLRC recommended against imposing a strict liability standard for misrepresentation or negligence.

genetic materials. As the law had failed to keep pace with science,[62] the OLRC endorsed the creation of a clear statement of policy, regulatory guidelines and location restrictions. The OLRC remained willing to defer many issues to the discretion of the physician within the confines of the patient/physician relationship. Physicians would determine the propriety of making gender information and gender selection available to parents. Physicians would also determine the propriety of placing multiple ova into women's bodies. The OLRC did not describe how selective reduction would impact upon the interests of potential children, the patients or the public.

The Commission proposed a series of external rules to govern control of fertilized ova. Gamete producers would provide consent and could limit the use made of their gametes. If donors provided unrestricted consent, they lost any legal right to control the use or disposition of fertilized ova. Consent would be revokable until fertilization, at which point a hierarchy of legal control based heavily upon biological origins would govern. Biological suppliers would determine the destiny of gametes. If both parents contributed to an embryo, they would jointly control its fate. Control would devolve to the survivor in the event that one contributor died. In the event of a disagreement, or if both contributors died, then control would pass to the possessor. If only one parent donated a gamete, control would rest solely with the donor because the non-contributor was a "stranger to the fertilized ovum." On default, control would revert to the professionals in possession of the gametes.

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[62] *Related Matters (Ont.), supra* note 31 at 190.

The OLRC supported embryonic research and experimentation up to the fourteenth day of development,[63] but only subject to external regulation and only in locations approved by the Minister of Health.

> We do recognize the fear of many persons that cloning and 'genetic engineering' are but one step removed from less dramatic research and experimentation. However, we do not believe that this view represents the weight of public opinion; nor do we accept the notion that science inherently cannot be controlled and that it must necessarily push beyond frontiers that are ethically acceptable to society. Medical and scientific research and innovation are hardly novel, notwithstanding what appears to be their accelerated rate of development in the second half of this century. Science has, in fact, been the subject of public control for quite some time, and manifestations of occasional aberrant behaviours should not be cited as proof of its inevitable unpredictability and immunity to regulation.[64]

This recommendation was based upon "widely recognized" agreement that embryonic research was needed to improve human welfare, refine IVF, reduce wastage, and prevent infertility and spontaneous abortions (especially of genetically normal embryos). Based upon the negative reports in other studies, the OLRC recommended that embryos subject to nontherapeutic manipulation should not be transferred into women for gestation. The OLRC disagreed about the propriety of implanting embryos previously subject to direct therapeutic intervention. Finally, the OLRC recommended a 10-year maximum storage period after which the holder would be under a statutory duty to waste them. The limit was adopted because of unknown effects of long storage and because of possible intervening social factors such as death, divorce or separation of parents.

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[63]The OLRC recognized that time limits on research were biologically arbitrary and might have therapeutic and social costs. They also noted an overlap between therapy designed to benefit patients directly and research and experimentation to acquire knowledge irrespective of direct or immediate application.

[64]*Related Matters (Ont.), supra* note 31 at 209.

c. Surrogacy

The OLRC described surrogacy as a special case, a fundamentally unique method of reproduction requiring a higher degree of regulatory intervention.[65] Special treatment was justified on several grounds: the possibility of emotional harm extended farther than with other procedures to the surrogate, her children and her spouse; the possibility of negative reactions to birth of a handicapped or impaired child; and, the potential exploitation of impecunious or otherwise vulnerable women who cannot refuse the money or "the blandishments of the person coordinating the arrangement."[66] These considerations suggested a cautious approach involving unique statutory safeguards and significant judicial intervention on a case by case basis.[67] Under the regulatory scheme, gestational contracts had to be written, contain certain provisions and be judicially pre-approved. Judges would determine the suitability of the parties based upon the medical need for the procedure, their marital status and parenting ability. Similarly the judge would assess the surrogate's ability, based on her likelihood to fulfill the contract, and the psychological vulnerability of the surrogate and her family. Judges would approve the rate of remuneration to prevent exploitation of the surrogate. In addition, judges would review previously negotiated contract provisions about insuring the surrogate, restrictions on her actions, prenatal screening obligations, custody in the event of separation or death of the intended parents, and the manner of transfer of the

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[65]Thirty two of the sixty seven recommendations dealt specifically with the regulation of surrogacy.

[66]*Related Matters (Ont.), supra* note 31 at 122.

[67]The OLRC also noted that surrogacy is regarded negatively in general and criminalized in many other jurisdictions, though the Commission criticised criminalization because of a lack of real support.

child.[68] Gestational contracts would be specifically enforceable regardless of the child's health unless, between conception and delivery, facts came to light showing that the contracting couple would be unsuitable parents. Like adoption agencies, surrogate agencies and for profit intermediaries would be regulated by the Ministry of Community and Social Services to prevent "offensive commercialism." Illegal arrangements could be regularized only through formal adoption. After criticising unwarranted criminalization of other procedures, the OLRC recommended the imposition of fines for evading this regulatory scheme. The OLRC avoided the issue of surrogates' abortion rights citing general legal uncertainty about all abortions.

d. Conclusion

The OLRC endorsed a high degree of professional deference, first to individual physicians, then to medical bodies, other existing regulatory bodies, and the judiciary. However, there is no substantive discussion about why some issues were better left to doctors while others warranted third party supervision, this is particularly true with respect to surrogacy. Further, this report did not address any theories of distributive justice, utility or equality as underlying principles to govern legal and medical systems. The OLRC gave little consideration to the patient/consumer perspective, to the conflict within the physician's role or the need to control the physician within the relationship. Further the OLRC failed to consider ARTs from the perspective of women or to recognize the disparate impact of ARTs. The OLRC often cites its perceptions of a majority consensus to justify its conclusions, despite also recognizing a lack of consensus on many issues and the deeply personal nature of these issues.

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[68] *Related Matters (Ont.), supra* note 31 at 259.

B. Federal Initiatives

1. National Health and Welfare Advisory Committee to the Minister: Storage and Utilization of Human Sperm, 1981[69]

Commissioned by the Minister of National Health and Welfare in 1977 to provide advice about the storage and use of human sperm and the propriety of commercial sperm banking, this Committee's work was cut short by significant funding reductions in 1978.[70] The Committee relied upon the views of geneticists, lawyers and physicians to form general conclusions. They accepted from the outset the view that AI was a socially acceptable practice and a beneficial medical procedure. However, they expressed concern that as AI demand increases, legislative protection of the couples and children may be required to ensure continued beneficial results.[71] The Storage Report is divided into three legal sections: legitimacy of AI children; standards for sperm collection and preservation; and, controls over centres providing AI.

First, to preserve privacy and strengthen the family unit, the Committee urged the enactment of uniform provincial legislation deeming AI children to be legitimate and permitting intended fathers to be registered inconspicuously on birth certificates.[72]

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[69]Canada, The National Health and Welfare Advisory Committee to the Minister, *Storage and Utilization of Human Sperm* (Ottawa, 1981) [Hereafter *Storage Report*].

[70]Under its terms of reference the Committee was to consider: the current and forecasted extent of storage and use of human sperm; methods of collection, preservation and reconstitution; the means to assess donors and recipients, to counsel prospective parents and to determine effects on children and family; the need to control importation of sperm; the biological, legal, medical, philosophical, religious and social implications of using stored human sperm; and evidence about the genetic and health effects of storing human sperm. *Storage Report, supra* note 69 at 71.

[71]*Storage Report, supra* note 69 at xi.

[72]Federal laws involving children would also be amended as necessary to apply to all children born through AI.

Second, the Committee recommended the enactment of protective national standards regulating the acquisition, preservation and importation of sperm similar to the standards governing other biological products.[73] The regulations would ensure that semen was free from infectious or transmittable diseases and met minimum quality standards; that detailed genetic inquiries had occurred to reduce the risk of genetic disease; and, that pregnancies per donor were limited. Further, the Committee recommended that its guidelines be reviewed after long term follow up studies. The Committee recommended that donors receive psychological, physical and genetic screening as well as counselling about ethical and legal issues, particularly potential liability and the personal impacts of genetic testing.[74] After counselling, donors would supply written consent confirming the completeness and veracity of health information and then undergo a physical examination and genetic testing. Donors would be compensated for inconvenience and expenses only. They would have no knowledge of or contact with any children. The Committee advised against permitting commercial suppliers to supply sperm arguing that private agencies were less permanent and less accountable.[75] The Committee called for a ban on sperm importation until foreign materials could be properly evaluated.

Third, the Committee proposed supply centre guidelines for record keeping, counselling, consent forms, insemination procedures and obligations should an abnormal infant be born.

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[73]As a reflection of the times the report did not specifically address HIV/AIDs and advised the exclusive use of fresh sperm citing the unknown effects of cryopreservation.

[74]Screening would detect nontrivial malformation, non trivial Mendelian disorder, recessive inherited genes, major genetic components within the family, and other genetic disorders.

[75]*Storage Report, supra* note 69 at 14.

These guidelines were intended to protect the donor, recipient and progeny. The Committee assessed the merits of linked records noting that they raised conflicts between potential genetic illness and congenital defects and the principle of anonymity.[76] Ultimately, the Committee decided that the benefits of maintaining linkable medical records outweighed the disadvantages. The Committee felt that if their legal status was uncertain, donors would not be willing to provide sperm without assurances of anonymity. To protect donor anonymity, the Committee recommended that doctors store the files separately in accordance with provincial laws for a specifically prescribed period covering at least the time within which most defects would become apparent. Further, the Committee recommended that the provinces enact uniform legislation to establish a board to inquire into legal claims arising from defects in children and other legal issues connected to AI.[77] Feeling that the guidelines really safeguarded the progeny rather than donors or doctors, the Committee also urged provinces to enact remedial laws to protect them from frivolous litigation and make them responsible for negligence and malfeasance only. These laws would ensure that physicians practised AI and that patients would not seek unregulated sources.

Turning from providers to recipients, the Committee recommended that potential parents receive counselling about success rates, the legal status of offspring, and other ethical and legal issues. Further, written consent forms would be required to document the couples understanding of the purpose of AI, the source and screening of sperm, the importance of

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[76]Linked records could be used to inform the donor of genetic factors for his future consideration; to prevent marriage within restricted degrees of consanguinity; to prevent negligent collection of sperm; and, to enable AI children to trace their genetic fathers. However linked records could also compromise anonymity.

[77]The board would be given the authority of a commission under the Federal *Inquiries Act*, R.S.C. 1985, c.I-2.

confidentiality, records, the risk of abnormal children, current laws, cost, success rates and the obligation to report about the children's health.

The report concludes with a brief outline of ethical issues raised by AI and commentary about the effects of AI on the family unit. The Committee observed that AI changes moral, social and interpersonal aspects of reproduction. While the Committee agreed that positive reports were largely anecdotal and often provided by protagonist doctors and successful recipients, they concluded that "AID rarely harms and may often strengthen the family."[78] They observed that while AI involved a huge intrusion upon the normal structure of marriage, it occurred on the limited level of genetic communication only because the "donor is not being given a right over the wife's body, much less over her person or her sexual communication of love and person to her husband."[79] After accepting the morality of AI within marriage, the Committee listed ten additional ethical issues with little or no comment.[80]

The report was quite general and vague, guiding principles were not articulated. The Committee simply accepted AI and advocated the development of industry standards and regulation for transactions involving human sperm. Despite the professed motive of patient safety, the Committee concentrated upon limiting the legal exposure of donors and physicians

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[78]*Storage Report, supra* note 69 at 44.

[79]*Storage Report, supra* note 69 at 36.

[80]These issues included limits on access based upon medical need, sexual orientation, marriage, and psychological factors. Additional issues relevant to donors were also raised: donor characteristics, proper testing standards, propriety of paying donors, and ensuring responsible donor behaviour. The Committee then questioned the advisability of secrecy, and propriety of policy formulation in a factual vacuum.

for much of the report. The report frequently calls upon the Provinces to enact universal legislation on key points such as liability, record keeping, legitimacy and dispute resolution. Like other early reports, this one included many unacknowledged assumptions. AI was considered only in the context of marriage. Potential conflicts were neither anticipated, nor addressed. The Committee addressed regulatory standards, and made many recommendations despite acknowledged factual and legal limitations.[81] In fact they suggest that the secrecy associated with AI and the lack of reliable relevant data may be an insurmountable obstacle to optimal regulation:

> In general, the very privacy of artificial insemination will preclude, in our culture, the recruitment of AID progeny in numbers sufficient to establish the effects of artificial insemination. As optimal studies may thus be impossible, the committee hopes this report will stimulate public awareness and a level of discussion that will result in the best quality of outcome within the law.[82]

2. The Law Reform Commission of Canada: Medically Assisted Procreation Working Paper 65(1992)[83]

Working Paper 65, Medically Assisted Procreation was released by the Law Reform Commission of Canada ("LRCC") as the third report of a series prepared to examine aspects of law and procreation and to promote public debate.[84] The first report, *Crimes Against the*

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[81] *Storage Report, supra* note 69 at 13-15.

[82] *Storage Report, supra* note 69 at 46.

[83] The Law Reform Commission of Canada, *Medically Assisted Procreation Working, Paper 65,* (Ottawa: Minister of supply and Services Canada, 1992) [Hereafter *Medically Assisted Procreation*].

[84] *Medically Assisted Procreation, supra* note 83 at 2-3. The third report was as an offshoot of the first as the LRCC decided further research was required about surrogacy, donor anonymity and national ARTs standards.

Foetus, Working Paper 58[85] addressed foetal protection under the criminal law.[86] The second, *Biomedical Experimentation Involving Human Subjects Working Paper 61*,[87] examined experiments involving human subjects, including human embryos.[88] The LRCC explained its reasons for the third report on ARTs as follows.

> The serious concerns that unsettle our society were also a factor in the

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[85]Law Reform Commission of Canada (Ottawa: the Commission, 1989).

[86]*Crimes Against the Foetus, ibid* first outlined the special treatment afforded foetuses even though they were not recognized as legal persons and then the strongly held, opposing views about foetuses (at 12):

> Such irreconcilable moral differences reveal the limits of law as a coercive instrument. By choosing one defensible moral position over another the state rejects the dissenting moral stance together with its religious underpinnings, if any. Societies like ours, which cherish freedom of conscience and individual autonomy, must obviously reject state imposition of one particular moral view, on others conscientiously holding opposing views equally defensible.
>
> Here, then, as elsewhere, criminal law must be used with restraint. It shouldn't be used to prevent abortions in circumstances where it is widely regarded as morally defensible. This doesn't mean, however, that it can't be used to protect the foetus where there is no justification for its destruction, that abortion is the only or best response to the dilemma of women pregnant against their will, or that the state should not in its role of furthering the common good protect the unborn through non-coercive means....

The LRCC applied a four part test to determine if criminal sanctions were an appropriate legal means of protecting foetuses. The test included the following questions: a) Does foetal destruction seriously harm other people? b) Does foetal destruction seriously contravene fundamental values? Second does it do so in such a way as to be harmful to society? c) Will enforcement measures necessary in criminal law themselves seriously contravene our fundamental values? d) Can criminal law make a significant contribution?

Ultimately the LRCC recommended the creation of a novel criminal offence: causing harm or destruction of a foetus (with exceptions to accommodate legal abortion) *Crimes Against the Foetus, supra* note 85 at 64. In this report, the LRCC distinguished foetuses from embryos created through IVF. This distinction was based upon the notion that embryos are not created in the womb and are therefore doomed, so their destruction or use for experimentation did not pose a problem. They did not question whether embryos should be brought into existence by deliberate acts in the first place (at 59). The LRCC described embryos as unique and suggested that if embryos are to be protected at all, then such protection should not be by ordinary criminal law relating to the person, but by special regulations (at 33).

[87]Law Reform Commission of Canada (Ottawa: the Commission, 1989) [hereafter *Biomedical Experimentation*].

[88]In *Biomedical Experimentation* the LRCC determined that federal law should define clear limits and protect basic values. In this report, the LRCC maintained a distinction between foetuses and embryos, allowing much more latitude to perform experiments on embryos than on foetuses (at 47). The LRCC recommended that embryonic experimentation be allowed up to the fourteenth day of development in federally approved facilities subject to prior approval of an ethics board and prior parental consent. They concluded that some experiments were so reprehensible that they should be prohibited under criminal laws (criminalized procedures included: production of embryos solely for research purposes, reimplantation of embryos previously used for experimental purposes, cloning, ectogenesis, parthenogenesis and crossing human and animal gametes at 59).

> Commission's decision to conduct this study. These concerns are often accompanied by demands for state intervention in the form of limits or controls justified by the scale of the costs involved, the need to impose limits on the development of medicine, the dangers of the marketing of procreation, the protection of the family unit and moral values, and the provision of safeguards against the exploitation of embryos, children, infertile couples and, especially, women.
>
> Such demands are made by individuals and groups whose interests are sometimes at odds with the needs of those who are most directly involved (infertile or sterile individuals, physicians, scientists and so on), and this can give rise to legal and social instability. In light of this instability and the inadequacy of other social controls, legislative intervention may be needed to define and regulate the relationships between the parties and the social groups concerned and thus to restore social equilibrium. In this area, perhaps more than any other, we must be careful not to act too swiftly. The first step is to establish whether there is in fact a need for reform; only then can the scope of the change be determined.
>
> Moreover, these social demands involve various aspects of the law which needless to say, are of special interest to a law reform commission: law as an instrument of social change; law as a protector of the fundamental values of society; and law as a regulatory agent.[89]

This report included greater detail than its predecessors about infertility and reproductive technology. It also gave more attention to difficult issues and risks associated with ARTs viewed from patients' perspectives.[90] The LRCC carefully divided the biological factors involved in procreation and furthering genetic lines, from the social construct of marriage. Throughout, the LRCC stressed the need to first assess the underlying acceptability of the procedures rather than immediately jumping into discussions about the optimal regulation mechanism, noting that "the focus upon controls and conditions clouds the ethical value of

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[89] *Medically Assisted Procreation, supra* note 83 at 2-3. In *Crimes Against the Foetus, supra* note 85 at 61 the LRCC stated:

> Regulation of medical practice falls under provincial jurisdiction. In the absence of uniform, national accreditation procedures and limits of practice for institutions, the possibility of interprovincial "procreative tourism" cannot be ignored and should be seriously examined.

[90] See *Medically Assisted Procreation Working Paper 65, supra* note 83 chapter 1.

the procedure."[91] The LRCC recognized several potential roles for the state including: dispute arbiter; health services provider; public financier; lawmaker; researcher; protector of public health safety and human life; strong, benevolent defender and promoter of human rights; or, administrator of birth records.[92] The LRCC also looked more intensely at existing legal controls, the functions of law and at specific legal and quasi-legal means of regulation along a spectrum of public involvement from state as oppressor to state as protector/liberator. The LRCC examined nonstatutory alternatives to ensure safe and uniform practices[93] and concluded that in the context of ARTs, positive law is sometimes needed to fill in gaps. However, the LRCC warned that:

> [a]ny legislative or state intervention in MAP should be aimed at promoting values that society holds fundamental such as the right to privacy and procreative autonomy, respect for the physical and mental integrity of patients, equality, the protection of life, special protection of children and those who are unable to protect themselves or who are vulnerable to harm or exploitation by reason of incapacity. Indeed, Canadian society tends to regard many of these values as fundamental rights that give legal content to the moral concept of human dignity.[94]

The LRCC also determined that professional controls, while useful in setting standards of good medical practice, were insufficient to control the provision of services (quoting the 1988 *Quebec Comite de Travail sur les Nouvelle Technologies de Reproduction Humaine, Rapport*):

> regulation of human reproduction technologies is a matter of social policy that must not be identified with the development of standards for the professional

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[91] *Medically Assisted Procreation, supra* note 83 at 49.

[92] *Medically Assisted Procreation, supra* note 83 at 114.

[93] Such as local, regional and national ethics committees; community controls; courts; professional standards; and, individual conscience.

[94] *Medically Assisted Procreation, supra* note 83 at 113-114.

> quality of the services." The task must therefore "not be left to the medical profession or to the other professions that are directly involved.[95]

The LRCC acknowledged federal jurisdictional difficulties.[96] The Commission also recognized that the principle of individual control, including the total freedom to assess risks and benefits governed natural reproduction and child upbringing in general. However, the LRCC ultimately recommended the enactment of a federal statute establishing an independent national regulatory agency to set minimum ART standards. A proposed statute, the *Medically Assisted Procreation Act* ("MAPA"), was appended to the report. Under MAPA, an independent agency would receive broad powers to certify and decertify clinics, set standards, collect uniform reports and ensure compliance.[97] According to the LRCC, an administrative agency would ensure flexibility in a complex developing area through systematic intervention, proper controls and a problem solving approach that statutes could not provide.

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[95] *Medically Assisted Procreation, supra* note 83 at 106 quoting from Ministere de la Sante et des Services Sociaux, *Rapport du Comite de Travail Sur les Nouvelles Technologies de Reproduction Humaine* (Quebec: The Department, 1988) at 152.

[96] The LRCC acknowledged that this was an area of shared responsibility - see for example *Medically Assisted Procreation, supra* note 83 at 163. The LRCC concluded that s 91 of the Constitution provided legislative power under the headings of public health and safety, interprovincial trade and criminal law the same powers it has used to regulate medical devices and drugs including prosthetic tubes and fertility drugs.

[97] The new agency would establish a system of certification for clinics and boards to regulate and control:

a. national standards for selection screening and storage of gametes and embryos;
b. annual reports and information registry;
c. requirement to freeze donated sperm and ensure AIDS screening;
d. duty to justify in writing the number of embryos implanted per treatment cycle;
e. duty to establish counselling services, their composition and duties;
f. content of records and duty to keep them;
g. duty to establish a system that allows linkage and protects anonymity;
h. duties regarding access to identifying and non-identifying information;
I. restrictions about allowable use and time limits, frequency of use, and importation;
j. prohibitions about selection and commercialization of gametes and embryos; and,
k. the conditions attached to the donation and exercise of control over gametes and embryo.

The LRCC used MAPA to impose certain absolute limits on treatment transactions. MAPA proclaimed that ARTs should be developed in accordance with the fundamental principles of equality and justice, and in a manner that respected the sanctity of life and the dignity and inviolability of the person.[98] MAPA also condemned commercialization in principle. As the existence of surplus embryos raised the possibility of commerce, MAPA prohibited commercialization of donations, allowed only reimbursement of costs for donations and limited provision of services to accredited nonprofit organizations.

The LRCC examined the likely impacts of the *Charter*, particularly s. 7 and s. 15 concluding that s. 7 might encompass a right to procreate.[99] However, the Commission reasoned that fundamental justice guaranteed under s.7 would provide procedural protections, rather than substantive entitlements. In addition, while there might be a right to be free of government intervention, subsidized access, particularly to capital intensive procedures such as IVF, was unlikely to be constitutionally assured. The LRCC addressed access and s. 15 atypically, focusing upon the general principle of patient autonomy in patient/physician relationships.

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[98]Section 3 of MAPA provides:

It is hereby recognized and declared that

a) medically assisted procreation technologies should be developed and used in accordance with the fundamental principles of equality and justice and in a manner that respects the sanctity of life and the dignity and inviolability of the person;
b) the use of medically assisted procreation technologies to select or avoid the transmission of genetic predispositions or traits is unacceptable except where specifically provided for;
c) commercialization of medically assisted procreation is unacceptable;
d) access to medically assisted procreation should not be limited on the basis of any criterion that relates to the family status, marital status or sexual orientation of the candidate;
e) a person should have the opportunity through counselling services to be fully informed prior to making a decision to use a medically assisted procreation technology; and,
f) the establishment of standards for public safety in relation to the use of medically assisted procreation technologies is essential.

[99]The LRCC relied upon *Eve (Mrs.) v.* Eve [1986] 2 S.C.R. 388 and the comments of Madame. Justice Wilson (now retired) in *Morgentaler* No.2 [1988] 1 S.C.R. 30. For further discussion see chapter 3 above.

According to the LRCC, if ART programs were established, access restrictions would be subject to *Charter* scrutiny. The LRCC concluded that infertile persons were not a discrete and insular minority entitled to constitutional protection, but warned that restrictions against certain subgroups of potential patients based upon sex, marital status, parental status and family status or sexual orientation could be legally suspect.[100] The LRCC rejected parental aptitude or stability as a screening criterion because it was not a consideration in the supply of other forms of procreative assistance (e.g. surgery for blocked fallopian tubes and prescription of hormones to stimulate ovum production), nor in natural procreation. The LRCC determined that women's rights to autonomy over their bodies and reproductive capacities enabled them to seek assistance regardless of spousal concurrence. Concurrence was only required to justify burdening a spouse with legal paternity. Furthermore, the spousal consent criterion discriminated against homosexuals and single persons by allowing access only to traditional family units (heterosexual parents in legally sanctioned unions).[101] However, the LRCC endorsed a statutory provision enabling discretion to restrict access to ensure that limited public funding was allocated properly amongst all health care areas.[102] MAPA also prohibited the use of ARTs for eugenic purposes. Section 6 prohibited the selection of gametes with specific qualities other than to prevent the transmission of a "serious genetic disease." Presumably serious genetic disease would remain a term of art to be defined

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[100]*Medically Assisted Procreation, supra* note 83 at 94.

[101]*Medically Assisted Procreation, supra* note 83 at 127 "protection of the traditional family should not be incorporated in legislation at the expense of the right to equality." In addition, the Commission reasoned that socially such restrictions were unwarranted given recent expansion in the definition of family.

[102]MAPA, s. 4 provides:

> No one should be denied access to medically assisted procreation services unless cost or scarcity of resources requires that candidates undergo a selection process. If a selection process is required, the family status, marital status or sexual orientation of the candidate should not be used as selection criteria.

by medical doctors.

The LRCC also determined that laws enacted to ensure patient safety (i.e. mandatory semen screening) were unlikely to raise *Charter* issues. So to protect patients, the LRCC proposed regulations establishing industry standards to combat the problems of low success rates, enable comparable data collection and evaluate programs. MAPA created a protected market within which only certified banks and clinics could import, store and use gametes and embryos.[103] The regulations dictated that certified providers collect and report standardized records of the true incidence of pregnancies, live births, spontaneous abortions, multiple pregnancies, and birth defects. According to the LRCC, a standardized national registry would alleviate the confusion that previously precluded vulnerable individuals facing a final chance to conceive from properly assessing programs and from providing truly informed consent. The agency would also be responsible for establishing uniform screening and storage standards to protect against the risk of transmitting infectious[104] or genetic diseases and the risk of consanguinity. The national agency would proscribe specific record keeping obligations, but MAPA placed a dual obligation upon clinics to keep linking records and to maintain donor anonymity. This system ensured the child's constitutional right to access nonidentifying information. The proposed act limited the national agency's powers over documents by providing that it gather only medical and genetic information "needed to obtain optimum medical care for the child; to meet the psychological needs of the child; to ensure

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[103]MAPA, ss.10-12.

[104]*Medically Assisted Procreation, supra* note 83 at 153.

proper clinical reports and to permit studies on the long-term effects of the various technologies used."[105]

The proposed act mandated pretreatment counselling to facilitate informed consent. In addition, suppliers were required to provide medical and psychological counselling during and after treatment.[106] MAPA addressed other issues arising after treatment had started. Like the OLRC, the LRCC was willing to leave the matter of simultaneous embryo transfer to the medical profession, reasoning that a statutory limit was arbitrary and would not ensure the safety of mothers or unborn children.[107] However, MAPA specifically required clinics to maintain records about transfers per cycle and to defend their decisions on this issue.[108] The LRCC concluded it was more important to establish a practical system to manage competing claims and potential uses of gametes and embryos than to resolve the theoretical issue of whether gametes and embryos were property or personalty. MAPA established a priority system based upon genetic contribution and previously documented intention. Donors and patients were compelled to document their intentions regarding future uses in general and in the event of specific contingencies such as death, abandonment of parental project, or expiry of storage limits.[109] Documented instructions could be changed up to the point of

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[105]MAPA, s.12.

[106]MAPA, s. 11.

[107]*Medically Assisted Procreation, supra* note 83 at 20-21. The LRCC noted that there was no agreement as to the acceptable rate of multiple pregnancies and that in the United Kingdom and Australia professional guidelines have been issued about maximum allowable transfers per cycle.

[108]MAPA, ss.7 and 13(2) and *Medically Assisted Procreation, supra* note 83 at 155-156.

[109]MAPA, s.8.

implantation. As for embryos, the proposed statute provided that if an embryo came from both members of the intended couple, they would share control. If the embryo came from one member of the couple and one donor, the contributing member would exercise sole control. If the embryos were produced entirely by donated materials, then control vested in the storage facility. The concept of control or proprietary interest was confined by the proposed statute to three uses: experimentation, implantation and destruction.[110] The LRCC also recommended the enactment of flexible regulations setting ultimate storage limits. Embryos were to be used or wasted within five years. Gametes were to be used or wasted within ten years. While the LRCC recognized that these limits were medically unnecessary and arbitrary, they were deemed essential for safety and sociological reasons and to account for the positive correlation between the passage of time and the potential for conflict.

Like many other commissions, the LRCC isolated surrogacy. While other treatments were called procedures, surrogacy was called a phenomenon. According to the LRCC, surrogacy contracts were void at common law, but could be incidentally enforced by established filiation laws. The LRCC also concluded that applying the *Charter* would be problematic because depending upon the biological origin of the child and provincial laws of legal parentage, the surrogate and the intended father could claim competing constitutional rights. The LRCC outlined the risks of surrogacy for surrogates, children and others. The Commission also reviewed the traditional arguments against surrogacy - the notions that surrogacy contravenes human dignity, harms children, jeopardises the traditional family; dehumanizes maternity; and,

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[110]*Medically Assisted Procreation, supra* note 83 at 141-142; MAPA, s.5.

devalues gestation, making women part of a production line. The LRCC noted that some view these risks as speculative and controllable, however, they concluded that human dignity precluded placing monetary value on a child and breached the principle that humans can never be objects of commerce. Surrogacy transactions were simply too similar to selling humans (a uniformly condemned transaction). Further, surrogacy raised the potential for exploitation through trade and commerce involving children. The LRCC bolstered its view that surrogacy contracts should be unenforceable based upon two family law principles: custody is determined by the best interests of the child; and, payment to arrange adoption is illegal. The LRCC recommended that all surrogacy contracts be declared null and void, leaving parentage to be determined by the courts independent of normally applicable filiation laws. A majority of the commissioners called for a criminal prohibition against intermediaries, but not parents, because parental incarceration was not in the best interests of the child.[111] Surprisingly MAPA contained no mention of surrogacy.

Finally in areas subject to provincial control such as succession and parentage, the LRCC found that parental rights and duties were allocated under existing laws on the basis of biological contribution and marital status. The LRCC urged the provinces to adopt uniform laws assigning parental roles to patients and their consenting spouses - to the exclusion of donors. The LRCC also suggested that children conceived posthumously should not have succession rights, unless they were explicitly mentioned in their intended father's will.

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[111]The minority disagreed, concluding that there should either be no prohibition, or a complete prohibition applicable to all participants.

The LRCC took a more incisive approach to policy formulation and regulation than many other reports. The LRCC did not merely rely upon mystic "uniqueness"to support its conclusions. Instead the LRCC enunciated potential guiding principles and values including the special status and moral value of embryos, individual freedom, equality and human dignity. In crafting policies, the Commission acknowledged that conflicts could arise from the application of those principles and then explicitly selected paramount values. Unfortunately, in some instances underlying reasoning is not evident, legal rules are magically produced after a mere recitation of the conflicting values, and pronouncement of a trump principle.

3. Royal Commission on New Reproductive Technologies: Proceed With Care, Final Report of the Royal Commission on New Reproductive Technologies (1993).[112]

The most extensive and controversial research and reform undertaking to date has been the Royal Commission on New Reproductive Technologies ("RCNRT"). On October 25, 1989, the RCNRT was constituted to study and report upon current and potential developments related to NRTs (considering in particular their social, ethical, health, research, legal and economic implications and the public interest) and to recommend appropriate policies and

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[112]*Proceed with Care: Final Report of the Royal Commission on New Reproductive Technology* (Ottawa: Minister of Government Services Canada, 1993) OIC No. P.C. 1989-2150 [Hereafter *Proceed with Care*]. *Proceed with Care* looked extensively into the causes of male and female infertility including: sexually transmitted diseases, smoking, age, delayed childbearing, exposure to harmful agents, alcohol and substance use and abuse, weight, eating disorders, excessive exercise, stress and endometriosis.

The Commission also assessed the impacts of medical interventions and drugs upon fertility. The mammoth report could itself be the subject of a thesis. This summary is not meant to be comprehensive, it is limited mainly to the legal aspects and recommendations affecting patient/physician relationships in the NRT context. Issues such as the causes of infertility, prevention, prenatal testing, judicial intervention in pregnancy, patenting, and the use of fetal tissue obtained in abortion are not addressed.

safeguards.[113] Its final report, *Proceed with Care,* was released more than three years later after much delay and controversy[114] and a cost of more than 25 million dollars. The 1200 page report included close to 300 recommendations as well as the dissenting opinion of one Commissioner.[115] It was accompanied by fifteen volumes of background research papers.

Proceed with Care was divided into three parts: a) the contextual background, guiding principles, and methodology of policy formulation; b) an examination of discrete topics such as medical conditions and specific treatment techniques; and, c) a reformatted summary of recommendations which divided regulatory control over NRTs amongst new and existing government departments, agencies and other groups. The RCNRT stood out for many reasons. It placed unprecedented and deliberate emphasis on previously unrepresented groups, particularly women because of the disproportionate impact of NRTs upon their bodies and

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[113] The Commission was charged with the responsibility of examining:

a) implications of new reproductive technologies for women's reproductive health and well being;
b) the causes, treatment and means to prevent male and female infertility;
c) reversals of sterilization procedures, AI, IVF, embryo transfers, prenatal screening and diagnostic techniques, genetic manipulation and therapeutic interventions to correct genetic anomalies, sex selection techniques, embryo experimentation and fetal tissue transplants;
d) social and legal arrangements, such as surrogate childbearing, judicial interventions during gestation and birth and ownership of ova, sperm, embryos and fetal tissue;
e) the status and rights of people using or contributing to reproductive services such as access to procedures, 'rights' to parenthood, informed consent, status of gamete donors and confidentiality and the impact of these services on all concerned parties, particularly the children; and,
f) economic ramifications of these technologies such as commercial marketing of ova, sperm and embryos, the application of patent law, and the funding of research and procedures including infertility treatment.

[114] Several of the original Commissioners sued the government and the RCNRT. They were removed and replaced. Some of the controversy is detailed in G. Basey, M. Eichler & A. Lippman Eds., *Misconceptions: The Social Construction of Choice and the New Reproductive and Genetic Technologies* (Ontario: Voyageur Publishing, 1994).

[115] Commissioner Suzanne Rozzell Scorsone's six point dissent is found at 1054 of *Proceed with Care, supra* note 112. She disagreed with respect to the propriety of creating educational programs to prevent sexually transmitted diseases, basing access solely upon medical indications, permitting embryonic experimentation, providing prenatal diagnosis, allowing children to access identifying information about their donors, and prohibiting judicial intervention in pregnancy.

social status[116] and also because "[t]he fact that women bear and are the primary caregivers of children remains the most profound factor defining women's role and society's expectations of them."[117] The RCNRT examined foreign legislation and reform proposals and drew upon this information to support its own conclusions.[118] The project also involved

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[116]*Proceed with Care, supra* note 112 at 41.

[117]*Proceed with Care, supra* note 112 at 250.

[118]The RCNRT also looked at other law reform proposals and legislation and found areas of virtually unanimous international agreement:

1. IVF and AI are legitimate medical responses to infertility and should be institutionalized by some national accreditation or licensing and record keeping system.
2. Informed consent is an essential precondition to treatment and to obtaining human gametes and zygotes.
3. Some embryo research is clearly unacceptable e.g. cloning human-animal hybrids; other forms are acceptable in first 14 days in vitro if they are strictly regulated and do not involve the implantation of zygotes subject to experimentation.
4. Use of donated gametes and zygotes is permissible.
5. Legal status of artificially conceived children should be regularized.
6. There should be a time limit on storage of gametes and embryos and decisions should be made in advance regarding contingencies of death or divorce by law or donor choice.
7. Commercial preconception agreements and financial inducements for gamete donors are unacceptable.

The RCNRT noted that sex selection for nonmedical reasons has been prohibited in several countries. The Commission also discovered areas of disagreement:

1. There were disagreements about the propriety of creating embryos solely for research and about the limits and purposes of research on embryos.
2. The criteria of access varied; most recommended social and medical conditions e.g. married, heterosexual, suitability as parents. Patient appeal mechanisms also varied.
3. Other than the OLRC, Canadian inquires and most other jurisdictions firmly reject commercial surrogacy, but they differ with respect to propriety and regulation of noncommercial surrogacy.
4. AI is generally regarded as a legitimate medical treatment, but there is less consensus about whether it should be monopolized by physicians.

The RCNRT also found some areas which showed developing views:

1. Opinions are shifting about maintaining secrecy to offspring and allowing offspring of assisted conception access to nonidentifying information.
2. There was increasing emphasis on the need for standardized and centralized record keeping on use of ARTs and for the use of regulatory apparatus to ensure the data collection function.

Finally, the RCNRT found certain gaps in other works including: the long term social impacts on particular groups; the impact of diversification in population; the social meaning of infertility; the medicalization of reproduction, economic considerations; ethical allocation of public funds; the role of commercial interests; and, the effects of globalization.

extensive efforts to amass public input and reliable scientific data.[119] This research revealed a patchwork medical situation characterized by inconsistent standards of practice, gross variations in access, discriminatory practices, and failures to adhere to established professional guidelines or to principles of evidence-based medicine. These inconsistences and failures had resulted in the provision of ineffective, unproven and unsafe treatments to women. Consistent with earlier reports, the RCNRT found a lack of domestic legislation specific to issues raised by NRTs and noted that the pre-existing family, health, contract and commercial regimes were inferentially and inconsistently applied by participants and the judiciary. The RCNRT concluded that ARTs and genetic technologies had far reaching social, ethical and public policy implications and constituted a distinct legal issue of national importance giving rise to federal constitutional jurisdiction under the Peace Order and Good Government clause.[120]

> NRTs possess a conceptual and practical integrity and distinctiveness. Their fundamental object is human reproduction, with all its distinct historical, social and ethical implications. Viewed as a biological function, reproduction is easily distinguishable from other matters of human health. It has particular social, significance, has particular ethical, political, and economic dimensions and creates particular legal relations and responsibilities. Thus, although health issues are certainly involved, numerous other individual and societal issues converge in reproductive technologies, necessitating a broad, inclusive approach to dealing with them.[121]

The RCNRT determined that NRTs should "proceed with care." Care would be provided by

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[119]According to the Chair, the RCNRT obtained input from over 300 scholars, 70 professions, and 40,000 Canadians through public hearings, panel discussions, workshops, surveys, written submissions, and toll-free phone lines. See *Proceed with Care, supra* note 112 at 135-139.

[120]This aspect of the report is thinly supported, see M. Jackman," The Constitution and the Regulation of New Reproductive Technologies" in Overview of Legal Issues in New Reproductive Technologies - Research Studies of the Royal Commission on New Reproductive Technologies, vol. 3 (Ottawa: Minister of Supply and Services Canada, 1993). It has been heavily criticised see chapter 3, *supra* and P. Healy, "The Criminalization of New Reproductive and Genetic Technologies" in L. Weir, ed. *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) 65.

[121]*Proceed with Care, supra* note 112 at 19.

the Parliament as guardian of the public interest through a two-pronged policy. First, criminal laws would set the boundaries of permissible activity by prohibiting certain practices.[122] Second, within licit boundaries, permissible practices would be managed by a more flexible regulatory system. According to the RCNRT, a self-regulatory model was not necessarily the best perspective from which to assess the implications of NRTs because to date this model had failed to create a uniform system sufficiently accountable to patients and others.[123] The Commission recommended establishing the National Reproductive Technology Commission ("NRTC"), an independent national agency.[124] The NRTC would be governed by a diverse 12 member board appointed by the Governor in Council.[125] Six subcommittees would assume responsibility to establish national practice standards for treatment and research, licensing, collecting information, monitoring practices and coordinating intergovernmental cooperation.[126] The subcommittees would be created and staffed by appointed boards including members of the NRTC. This national agency would develop and oversee coherent, comprehensive and effective national standards and monitoring devices in this rapidly

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[122]The *Criminal Code* would prohibit: for-profit activities; advertising as a commercial intermediary to surrogacy; ectogenesis; cloning; creating hybrids; some uses of fetal eggs; and, providing unwanted medical treatment or interference with the physical autonomy of pregnant women.

[123]*Proceed with Care, supra* note 112 at 57.

[124]An independent federal agency was considered superior to provincial efforts or national regulation through existing federal departments because it would be all inclusive and report directly to Parliament. Although the final recommendations involve cooperative participation from both levels of government.

[125]At least six members (including the president) would be appointed for five years, full time terms (renewable for between one to three years). Members would to be experts with diverse backgrounds. Women were to compose at least half of the members. Members would also represent and have knowledge of persons with disabilities, infertile persons, racial minorities, aboriginals and economically disadvantaged persons.

[126]The six sub-committees would assume responsibility for developing standards and guidelines and for regulatory oversight in the following areas: sperm collection, sperm storage and distribution and the provision of AI; assisted conception services; prenatal diagnosis; human zygote/embryo research; the provision of fetal tissue for research; and the prevention of infertility. The plan is detailed in *Proceed with Care, supra* note 112 at 1023-1033.

changing field. It would provide maximum opportunities for public participation and public accountability. It would also assure Canadians that government and professional bodies would fulfill their responsibilities to protect citizens from unethical, unproven or unsafe procedures.

NRTs would be legally classified as medical practices and would be provided exclusively by nationally licensed facilities operating within the existing public provincial health care systems. Compliance and standardized practices in providing services, counselling and reporting results would be assured through a system of compulsory renewable licensing. Any breach of license conditions would be punishable by license suspension and in some cases criminal prosecution.

a. A Novel Framework for Policy Development: The Ethic of Care and Guiding Principles Approach

Proceed with Care emphasized the need for enforceable ethical standards and a new approach to policy formulation. The RCNRT found this new approach in an "ethic of care model" within which a set of guiding principles "informed and infused" the process of recommendation formulation and maximized the possibility of consensuses while minimizing potential conflicts. Through public consultation and earlier reform initiatives, the Commission identified eight guiding principles: individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, noncommercialization of reproduction, appropriate use of resources, accountability and balancing of individual and collective interests. While explicitly a framework for principled policy formulation, the principles themselves were inconsistent and rife with implicit assumptions and biases. The RCNRT not only rejected the use of a single overarching ethical theory upon which to build a principled model, it also

rejected the use of a set hierarchy or means to deal with conflicts amongst the principles.[127] The RCNRT further clouded its overall methodology by reformulating its goals stating at one point that its "priority, therefore, is on helping human relationships to flourish by seeking to foster the dignity of the individual and the welfare of the community."[128]

b. Specific Treatments and Recommendations

i. Procreation and Infertility.

The RCNRT found infertility was widespread, affecting approximately 250,000 Canadians at any time. As research revealed that Canadians consistently stressed the importance of having a family, "the Commission concluded that a responsible and caring society should seek ways to recognize and support the desire of individuals and couples to have children."[129] If safe, ethical and effective means were available to help Canadians have healthy children, then the RCNRT felt that the government ought to consider providing them in a manner consistent with the *Charter* and the principles established in the *Canada Health Act*. To ensure noncommercialization, equity, and fairness, the RCNRT recommended that NRTS be available exclusively within the existing public health care system.

ii. Fertility Drugs.

The RCNRT closely examined the use and regulation of fertility drugs as they were the most common form of infertility treatment and were often used in concert with the other ARTs.

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[127] *Proceed with Care, supra* note 112 at 53.

[128] *Proceed with Care, supra* note 112 at 52.

[129] *Proceed with Care, supra* note 112 at 163-164.

While recognizing that fertility drugs, were regulated as pharmaceutical substances, the RCNRT endorsed additional controls. Concerned about the lack of systematic research on the side effects and the risks of fertility drugs (particularly the risks of higher order births and premature births),[130] the RCNRT suggested that the NRTC be empowered to develop standards and guidelines for the prescription of fertility drugs and for the provision of professional nondirective counselling.[131] Licenced clinics would be required to release prescribed information to the NRTC which would then analyse and protect the data and publish annual results. The NRTC would also monitor the promotional activities of drug manufacturers and oversee privately-funded studies about adverse drug reactions.

iii. Assisted Insemination.

While AI had become more open and acceptable, the RCNRT determined that it nonetheless raised the same social and ethical implications as other NRTs. Therefore a standardized system governing the provision of AI would be created to protect the health of recipients,

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[130]According to the RCNRT, *Proceed with Care, supra* note 112 at 419-420:

> Fertility drugs occupy a unique place in the infertility treatment spectrum. Many do not consider fertility drugs to be a 'new reproductive technology," yet fertility drugs are developed and used to act on the same biological processes as new reproductive technologies, with the aim of correcting some of the same disorders, and they have the same far-reaching implications - they could potentially affect not only women who use them but also their children.
>
> Fertility drugs are the most prevalent infertility treatment and are used in most other assisted conception techniques. The prevalence of fertility drug use makes it important to collect information on their short- and long- term outcomes. The side effects and long-term outcome of fertility drug use have implications for society that are just as great as those of drugs used to treat heart disease or cancer.

[131]With input from relevant professional bodies such as the SOGA. In addition professional groups would disseminate similar guidelines and information to physicians practising outside licensed clinics.

their families and offspring.[132] The collection, storage and distribution of sperm would be controlled through licensing agreements with the NRTC.[133] Licences would be issued for terms of up to five years. They would be renewable and revocable (at any time for breach of specified conditions). Providing services without a license would constitute an offence subject to prosecution. All licensees would be subject to detailed disclosure obligations. All confidential records would be maintained by the NRTC. The RCNRT evaluated the relative merits of three disclosure systems: full disclosure of all information; a dual system where recipients could select identified or anonymous donors; or an anonymous donor scheme allowing disclosure of social, medical and genetic information, but not identity (absent some pressing medical need). The RCNRT opted for the anonymous system, reasoning that it would ensure continued donation, satisfy the needs of the recipient family and maintain equality amongst all AI offspring.

Research revealed that the current system of controlling the provision of AI through professional guidelines was inadequate. Inconsistent, dangerous and unethical screening practices were occurring.[134] In the interests of patient safety, the Commission recommended screening standards including tests for communicable diseases such as AIDS. The RCNRT stressed the importance of obtaining fully informed consent prior to donation and

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[132]For example, the RCNRT recommended that women not receive invasive exploratory or diagnostic techniques, or adjuncts such as hormones unless there is an established indication of female infertility, *Proceed with Care*, *supra* note 112 at 484.

[133]See *Proceed with Care*, *supra* note 112 at 470-488 for an overview of the new system and the role of NRTC.

[134] Screening for diseases and practices of donors varied greatly: see *Proceed with Care*, *supra* note 112 at 450 which provides a table of screening practices of AI programs in Canada in 1991.

recommended that donors provide written acknowledgement of the short and long term implications before donation. Consistent with the guiding principle of noncommercialization, the RCNRT reasoned that compensation should not create a financial incentive to donate. To avoid dehumanizing effects, donors would only be compensated for inconvenience and time.

The RCNRT noted that physician gatekeepers had used their personal beliefs and perceptions about community standards to establish access criteria. Their views resulted in variable practices and the disproportionate exclusion of single women, lesbians, and individuals with below average intelligence, doubtful parenting ability, or low incomes. So while the RCNRT recognized that access to AI should be based solely upon medical considerations,[135] it also concluded that access to these publicly funded services must be provided in a manner consistent with human rights laws and the *Charter*. *Proceed with Care*, supported exclusion only if proven to be in the best interests of potential children and to be justifiable under s.1 of the *Charter*.[136] Unfair exclusion, they argued, would put these groups at risk of resorting to unsafe illegal services.

To maintain patient autonomy, the RCNRT recommended prescribing mandatory ongoing counselling of patients about their diagnosis, chances of success, details of treatment, and about nonmedical alternatives, costs benefits and possible outcomes. The RCNRT also advocated the enactment of uniform provincial statutes assigning parental status and

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[135]Earlier commissions suggested that the most controversial aspect of AI was access for single and lesbian women.

[136]*Proceed with Care*, *supra* note 112 at 456-457.

obligations. Under these uniform laws, donation severed parental rights and responsibilities. A consenting spouse or male partner of a recipient would become the legal father, unless at the time of birth he disavowed paternity because he did not know about AI, or he had consented under duress, coercion or fraud, and had acted as a father only because he believed he was the genetic father. In the event of disavowal, the child would be left without a legal father. If a male partner or female partner of an AI recipient subsequently acted as a parent, then the best interests of the child would determine parental rights and duties.

iv. IVF

Despite established professional guidelines, IVF practices varied greatly across Canada with little apparent accountability for these variations. Although IVF had only been proven effective to treat blocked fallopian tubes, it was used in many more situations, some "inappropriate and unethical" such as testing male fertility, and facilitating postmenopausal pregnancy or surrogacy. Further, the self-regulating paradigm had led to unacceptable record-keeping practices which precluded meaningful scientific evaluation or patient participation.[137] As with AI, equitable access to IVF was a problem for rural inhabitants, low income groups and many other groups.[138] Concerned about the high costs of IVF, its low success rates and the apparent misuse of the technology, the RCNRT recommended strict controls through mandatory licensing.

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[137] *Proceed with Care, supra* note 112 at 534-535.

[138] *Proceed with Care, supra* note 112 at 552. The most probable reasons for refusal include: doubtful parenting ability, psychological immaturity, lack of partner or husband, sexual orientation, below average intelligence, physical disability, low income or the existence of other living children.

Licensing providers would guarantee uniform national standards of practice and record keeping, while preserving the best interests of the patients in conformity with the RCNRT's guiding principles. This system would also directly affect autonomy within patient/physician relationships. Access to IVF would be determined by legitimate medical criteria without discrimination based on factors such as marital status, sexual orientation or economic status. Licensees would define "success" as the probability of a live birth per a single treatment cycle and would submit annual success statistics to the NRTC and to patients. IVF would only be offered after male fertility had been assessed and less intrusive or costly options had been considered, but tubal surgery would not be a prerequisite. The procedure would be offered only to women with a prior diagnosis of complete fallopian tube blockages from disease, defect or surgical sterilization. IVF would not be available to women past the usual age of menopause. However, IVF could be offered for other indications as an experimental procedure subject to NRTC approval. After obtaining informed consent specific to selective reduction, licensees would be allowed to transfer up to three zygotes per cycle.[139] Licensees would also require NRTC approval to perform pre-implantation diagnosis on zygotes. Determination of sex for nonmedical reasons would be prohibited. Providing services without a license and compliance with conditions of license would constitute offences subject to license suspension and criminal prosecution.[140]

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[139]Recipients would also receive counselling about the possibility of triplets to avoid the physical and psychological risks of selective reduction. Recipients would provide written consent about the number of zygotes to be transferred.

[140]The RCNRT recommended prohibiting unethical practices through criminal sanctions, *Proceed with Care*, *supra* note 112 at 499.

v. Excorporal Eggs, Embryos and Embryonic Research

The RCNRT was adamant that reproductive material should never be characterized as property because objectification violated the guiding principle of human dignity.[141] The commission pointed to a clear international consensus that the buying and selling of zygotes and certain types of research were inconsistent with respect for human life. In addition, buying and selling could alienate women from their bodies and promote the exploitation and commodification of women and children. Therefore, the RCNRT recommended that the sale of human eggs, sperm and zygotes be prohibited under threat of criminal sanction.

Finding no accurate records on the incidence of egg donation in Canada and no laws to regulating embryo research, the RCNRT again concluded that professional guidelines were inadequate control mechanisms. The Commission endorsed the promulgation of clear legislation to govern zygotes, embryos *ex uteri* and to augment the RCNRT licensing system which controlled the use of eggs and embryos. Under the new law, the two gamete suppliers would jointly determine the fate of zygotes through the execution of standard consent forms with set instructions in the event of certain contingencies such as divorce or dispute.
Citing the unknown effects upon children, the RCNRT recommended that zygotes should not be stored for more than five years or beyond the death of one of the gamete donors.[142] The

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[141]The RCNRT felt that legal rules were required to ensure that they were treated with respect as a form of potential human life, but that ownership was obviously inappropriate. For the RCNRT ownership meant an individual could sell, destroy, give away, bequeath, experiment, store and share in profits of research therefore a pure property law regime was clearly not acceptable, *Proceed with Care*, *supra* note 112 at 627. However, the RCNRT does not discuss why any of these procedures would be clearly unacceptable, it is presented as a self evident truth.

[142]The RCNRT cites unknown effects as a justification for some rather arbitrary decisions.

RCNRT recommended prohibiting altruistic donations[143] and designated donations.[144]

To preserve patient autonomy, consent would be sought before ovum retrieval. Altruistic donation would never be a condition of treatment, ovum donation would be allowed only if the woman was undergoing surgery in any event.[145] Given the restrictions on ovum donation, payment would be prohibited. Ovum recipients would also be obliged to execute special consent forms as eggs could not be frozen and their insertion would necessarily involve the risk of infectious disease transmission. Concerned that ovum donation could be used to expand the human reproductive lifespan rather than to overcome infertility, the RCNRT recommended that women of postmenopausal age not be allowed to receive donated eggs. The Commission justified age restrictions based upon concerns about whether older women were physically and psychologically prepared for the demands of pregnancy and parenthood, as well as concerns about the resulting child. The RCNRT recommended the adoption of record keeping protocols to preserve nonidentifying information (similar to the AI scheme) and the enactment of provincial laws deeming gestating mothers to be legal mothers, leaving ovum donors no interest in the children.

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[143]Altruistic donation was not considered to be ethical because one individual undergoes invasive surgical procedures with associated risks for the benefit of someone else. Voluntary aymous donation is acceptable only if the person is undergoing the procedure in any event.

[144]Designated donation is not permitted because of potential for coercion and exploitation of donor and because of potential adverse effects on the resulting child (the RCNRT felt there was reason to believe this could cause considerable difficulties amongst the child and its parents, the child and its genetic mother and the social parent and the egg donor). This is presented without rational support.

[145]The RCNRT stated that women seeking infertility treatment must understand and discuss their consent and must be specifically counselled about long term effects of donation, particularly if their own treatment is not successful. Further patients must be informed that a decision not to donate could in no way jeopardize or affect their current or future care.

The RCNRT also looked specifically at the use of human embryos for research purposes[146] and recommended allowing controlled experimentation[147] until the fourteenth day of development as a legitimate, although arbitrary, compromise.[148] Citing unknown effects, the RCNRT recommended limiting patient autonomy by prohibiting the implantation of embryos subject to manipulation. The Commission advocated criminalizing unacceptable forms of experimentation including: ectogenesis, cloning, creating hybrids, and transfering human embryos to other species. The RCNRT also condemned research into genetic alteration of human zygotes or embryos because the risks vastly outweighed potential benefits and because safer and more appropriate ways existed to manage the risk of passing on genetic disorders.[149]

vi. Preconception Arrangements.

The RCNRT described surrogacy as an undertaking to conceive and bear a child with the understanding that it would be raised by someone else. The RCNRT concluded that surrogacy agreements would not be legally valid under current laws for reasons of public policy and that such contracts would be overridden by the family law principle that children's best interests govern custody matters. The Commission accepted that there were mixed views on

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[146]They noted that other countries had enacted laws about embryonic experimentation, some countries allowed it for up to seven or fourteen days, others banned it. Some allowed it on surplus embryos. Some allowed the creation of embryos for research. The RCNRT also found that if permitted, it is generally subject to national monitoring through legislation, licensing or accreditation.

[147]If allowed the following restrictions apply: projects must be approved by an ethics committee; informed consent of donors must be obtained prior to donation, experimental embryos cannot be returned to a uterus; there must be no alternative means to obtain the needed information; zygotes cannot be bought or sold; and, the aim of the research should not be commercial profit.

[148]*Proceed with Care, supra* note 112 at 636.

[149]*Proceed with Care, supra* note 112 at 637-638.

surrogacy,[150] but emphasised that apart from the OLRC, most Canadian and international reports discourage and even criminalize commercial arrangements. The RCNRT condemned commercial arrangements which commodified children and reproduction. They found it fundamentally repugnant to deliberately create a child and give it up in exchange for money. Surrogacy would enable women to alienate aspects of themselves that should be inherently inalienable. Second, the RCNRT rejected the view that surrogacy enhanced female autonomy noting in any event that personal autonomy is never absolute. According to the RCNRT, it harmed the autonomy of the gestational mother as her behaviour would be controlled and she could be coerced by brokers acting on behalf of commissioning couples. Third, the RCNRT felt that surrogacy harmed society and women by diminishing the dignity of reproduction and undermining societal commitment to the inherent value of children. The RCNRT concluded that surrogacy was not a medical necessity as it was unacceptable that the gestating woman should bear all the medical risks of pregnancy and birth, while all the benefits accrue to the commissioning couple. Fourth, in accordance with their ethic of care framework, the Commission found surrogacy unacceptable because it was too likely to produce conflict. The RCNRT also condemned noncommercial arrangements arguing that making a gift of another human being offended the human dignity of the child and could create damaging relationships especially if the gestational mother remained in contact with the child.[151]

According to the RCNRT, no regulatory system could overcome the basic affront to human

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[150]Interestingly, the RCNRT notes that the medical profession supported surrogacy in "medically valid" circumstances (i.e. for patients with no uterus, cervical or uterine cancer, malformed uterus, or medical condition such as sever hypertension, diabetes or heart disease), *Proceed with Care, supra* note 112 at 680.

[151]Openness and contact has become acceptable and even encouraged in adoption situations.

dignity occasioned by the commodification of children and the commercialization of reproduction through surrogacy. Therefore, the Commission recommended criminalization of advertising for surrogates, acting as an intermediary to bring about a contract and receiving payment or commercial benefit for participation. The RCNRT also recommended changes to provincial laws rendering such contracts unenforceable by deeming the birth mother to be the legal mother and allowing her to relinquish her maternal rights only after a minimum waiting period (similar to adoption). In addition, provincial laws would be amended to ensure that assisting in surrogacy would become a disciplinable offence for medical professionals.

vii. Prenatal Diagnosis and Gene Technologies

The RCNRT examined genetic procedures at three stages: pre-conception, pre-implantation and prenatal. The Commission considered four specific procedures: diagnosis of genetic diseases and fetal anomalies present from birth; testing for late onset disorders and susceptibilities; sex selection; and gene therapy technology to enhance desirable traits and to cure genetic disease and anomalies.

The RCNRT noted great public concern that science had outpaced society. The procedures promoted abortion, further medicalized pregnancy, changed attitudes toward the disabled, made women responsible for bringing perfect children into the world, and created the potential for subsequent discrimination. As with NRTs, research revealed huge, unjustified variations in referral and treatment practices as well as insufficient professional accountability. The RCNRT also found significant conflicts between patient concerns and professional concerns. The Commission stressed the importance of counselling and fair access. It

recommended prohibiting some practices and strictly regulating others within the NRTC five year renewable licensing model. NRTC sub-committees would set national guidelines and standards for licensees. Prenatal screening and selective abortion would only be available for serious genetic and congenital anomalies. As susceptibility testing alone provided little therapeutic information, the Commission concluded that was an unacceptable use of resources, and should be prohibited. Licensees would not be allowed to genetically alter human zygotes or embryos. The RCNRT also condemned nonmedical sex selection at all stages.[152] In their view, allowing sex selection for nonmedical reasons would perpetuate biases and the subrogation of women. Sex selection violated the guiding principles of respect for human life and dignity, sexual equality, protection of the vulnerable, balancing individual and collective interests and responsible use of collective resources. In this case respect for cultural diversity would yield to the other principles. The RCNRT also recommended that the introduction of corrective DNA into somatic cells or germ cells should be strictly controlled. Research would be subject to review and approval by the NRTC Prenatal Diagnosis Subcommittee. Projects involving the alteration of DNA of human zygotes and embryos would not be allowed. The Commission condemned the use of genetic alteration to enhance desired qualities citing unanimous public opposition to enhancement of normal levels of intelligence, strength, beauty or other traits.

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[152]Preconception sex selection or sex selective insemination was viewed as an intrusive and unproven technique that worked for boys better than for girls. According to the RCNRT, it violated the equality principle; was not medically necessary; and therefore, represented a misuse of resources. Pre-implantation diagnosis was described as an invasive procedure with no medical value. It was an unethical and inappropriate use of resources. Effectively the RCNRT banned the use of IVF for sex selection or for any other nonmedical reasons. *Proceed with Care, supra* note 112 at 888 there is a rare discussion of the best legal vehicle to prevent sex selective abortions.

viii. Conclusion on Proceed with Care

Given the extensive mandate of the RCNRT and the magnitude of the project, *Proceed with Care* provided disappointingly few specifics. The report merely outlines a skeletal description of a national regulatory agency, leaving many difficult details for later development. No model legislation or precedent forms were included. There is a disappointing lack of discussion about the function and merits of alternative legal mechanisms. Criminal sanctions were proposed without a discussion of the existence or merits of other legal options. Given its professed emphasis upon women, the RCNRT also failed to adequately account for contrary views or to deal with redress mechanisms for patients through tort law and other statutory appeal and judicial review processes.

Although the unprecedented research efforts and the novel "ethic of care" model suggested a more thoughtful analysis than earlier reports, this expectation was not fully borne out in *Proceed with Care*. While purportedly a framework for principled policy formulation, the ethic of care principles were inconsistent and biased. The ethic of care could be used to rationalize any policy stand.[153] The RCNRT often unsystematically cited the ethic of care principles to formulate and bolster recommendations based upon thinly supported ethical pronouncements or apparent public support.[154] Many contentious issues are swept aside as self evident or fundamental truths. The spectre of unknown effects and the dangers of illicit activities were also cited without supporting rationale to justify sweeping moral

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[153]See Healy, *supra* note 120.

[154] Although the Commission repeatedly noted the lack of a consensus concerning almost all issues, isolated excerpts of individual opinions are incorporated throughout *Proceed with Care* and are often relied upon to justify specific controversial conclusions.

determinations. The RCNRT, like many predecessors, defined human reproduction as a unique topic not amenable to existing legal frameworks and then advocated an "individualized" approach to policy formulation that did not yield internal consistency, defensible coherent policies or a logical "ethic of care."

The RCNRT failed to establish that NRTs are a distinct subject area amenable to substantive federal legislation or to consider the efficacy of existing or modified provincial and national control mechanisms. Despite noting that ARTs involve both social and medical aspects, from the outset the Commission categorized NRTs as medical services which could only be ethically provided within the confines of the existing publicly funded and regulated system. Further, the Commission began without clear explanation from the premise that profit motives were inherently unacceptable even for those who could not participate in the public system.[155] Then these essentially economic concerns were translated tautologically into a moral justification to limit the availability of ARTs without adequate explanation. While ethical principles suggest that health resources must be used efficiently in a macro sense, it is not clear that this principle precludes the provision of ARTs in the private market context.

C. Conclusion

The Canadian law reform reports reflect twenty five years of technical, legal and social

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[155]The RCNRT devoted an entire chapter to the private sector and its impact on "the ethic of care model." Their research revealed that there was not a large amount of private sector interests, but they noted that commercial interests can have significant impact on the way NRTs are developed and disseminated especially as Canada is so close to the United States. The RCNRT determined that NRTs could not be left to market forces, as individuals are disadvantaged due to less medical knowledge and regulation is needed to resolve conflicts for the benefit of the patient. They concluded that having children was as important or more important than other publicly funded services so it should be provided within the public system *Proceed with Care*, *supra* note 112 at 716.

developments. The collection varies greatly in every respect including terms of reference, ideology, research methods, detail of analysis and conclusions. However, trends and common elements are evident. All the reports, except one, view ARTs within the medical context.[156] More recent reports tend to consider perspectives other than those of the medical providers. All recommend filiation laws for the children conceived through ARTs. All reports emphasize privacy.[157] All support some measure of external regulation. Many recommend screening and pretreatment counselling in addition to licensing systems. Provincial reports tend to assign regulatory controls to existing provincial agencies, while federal reports support the constitution of a national agency to assume the majority of regulatory responsibility.

All commissions agree that the best interests of the children of assisted reproduction are key. At a minimum, this principle required that their legal status be codified in uniform provincial statutes specifying legal parentage. While the proposed statutory rules are more complex in later reports which include special exemptions, all commissions recommend gestation as the trigger of legal maternity and consent as the trigger of legal paternity. There is an almost complete consensus that the act of donation severs parental responsibility.[158] The interests of children are also cited as a rationale for shrouding ARTs in secrecy.[159] Secrecy is also frequently justified based upon the view that donation is contingent upon anonymity. Secrecy

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[156]The British Columbia Commission recognized the medical aspects but viewed AI , a family law context.

[157]However, most also support the maintenance of linkable records and some measure of tracking by physicians or regulatory agencies.

[158]The LRCS assigns paternity to donors who knowingly donate to a single woman or a married woman without spousal consent.

[159]The merits of absolute anonymity have been contested in some foreign states and abandoned with respect to adoption.

would be preserved by anonymous donation, matching conspicuous characteristics of donors and intended parents and revising vital statistics data to surreptitiously regularize birth certificates. One commission proposed a novel statutory tort to compensate for pain caused by the disclosure of donor identity. While interests of children are touted as paramount, not all recommendations support their interests. Access restrictions preclude birth of children into certain families, selective reduction is not banned, nontherapeutic experimentation is not condemned and donor anonymity prevails over offspring interests in many instances.

The commissions also emphasized the importance of counselling and full, informed consent. They specify the information which must be disclosed to participants before treatment in order to perfect consent. Most of these proposals merely codify the existing common law requirements. Some reports do incorporate novel elements. For example, laws define success precisely to protect patients and reduce their information deficits. Further, the consent process is seen as an opportunity to anticipate and document instructions in the event of specific contingencies to avoid future conflicts. Consent provisions are more detailed in the reports which consider conflict over excorporal materials and control over their use.

Access is addressed in all reports. While all research into access revealed practical striking inequities, no report endorses a positive, unrestricted entitlement to ARTs. Some reports include implicit restrictions by considering ARTs solely in the context of heterosexual marriages. Other reports emphasize that marital status should not determine access. Fewer reports go further and recognize the constitutional rights of other groups such as lesbians and single women. The reports are sharply divided upon whether or not parenting ability is

relevant to the issue of access. Most recently, the RCNRT attempted to use medical considerations as a balanced filtering device. This view is deceptively neutral. It obviates key factors: that the evaluation of medical need is often subjective and value laden and that the causes of infertility are not always morally neutral. The RCNRT was also prepared to make access conditional upon prior treatment and age. Three reports recognized the need for an external appeal process for aggrieved potential patients.

The need for donor screening procedures to ensure the safety of recipients and their children is universally endorsed. Some commissions argue screening should be left to the judgement of individual physicians, while others recommend the independent formulation and enforcement of industry standards to reduce the risk of transmitting disease or genetic impairment and to limit the number of children created from a single donor. While the commissions conclude that donors should have no contact with recipients or offspring, they nonetheless endorse the maintenance of linkable records and some degree of tracking. The rationale for tracking information and the situs of control over information varies. Linkable anonymous records[160] are endorsed for many reasons: to assist the recipients and offspring in the event medical histories are needed for treatment; to provide information to donors for consideration in their own reproductive decisions; to prevent widespread transmission of disease or defect; to prevent consanguinity in subsequent marriages; and, to satisfy children's desires for nonidentifying information about their genetic heritage. Some commissions leave custody and control of circulation amongst the parties to the discretion of medical

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[160]One commission was prepared to allow designated donation which would enable participants to know the donor.

practitioners, while others felt the custody should lie with an independent agency and circulation should be explicitly restricted.

Early commissions are narrowly focussed and assign law a remedial function, leaving contentious issues to incremental evolution in the common law tradition. Later commissions are less willing to simply accept that ARTs are morally sound or to leave many material issues to the stewardship of professional judgement within the self-regulatory model.[161] Later commissions are more apt to use external regulation as a proactive measure to address specific problems and contingencies such as posthumous conception and sex selection. While the reports show a definite trend away from professional deference and toward external regulation, the movement may be somewhat cosmetic as the commissions all categorize ARTs as medical procedures and affirm the monopoly of licenced physicians. Physicians are still responsible for key decisions concerning medical need and the meaning of genetic impairment or defect. All models contemplate that the medical profession will play a dominant role in independent regulation.

The reports touch upon some of the inherent conflicts facing physicians, but miss the opportunity to fully explore the struggle between self-regulation and externally imposed legal controls. Many early reports are quite concerned with ensuring that physicians will not be

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[161] Absolute limits on the number of embryos that may be transferred in a single cycle is a pivotal issue which illustrates this trend. It was considered purely a matter of professional judgement by the OLRC. The LRCC later agreed, but cautioned that physicians must provide evidence to support their medical opinions. Then the RCNRT advocated a regulatory maximum of three embryos per cycle and mandatory pretreatment counselling about selective reduction and triplets. No report goes so far as to set a mandatory limit on an even more important issue: the number of embryos that may be created at a single time.

seen as legal guarantors of perfect babies. Later reports seem more prepared to leave the standard to general tort and contract law principles even though with technological advancement physicians are more able to manipulate the randomness of procreation. Patient autonomy and legal rights are more prominently featured in later reports written in the 1990s, although all reports advocate arbitrary limits to these principles.

Certain technologies and situations trigger stronger responses, including: surrogacy, the existence of excorporal embryos and the genetic manipulation of reproductive materials, particularly embryos, for therapeutic and nontherapeutic purposes. Surrogacy is the black sheep of ARTs. All commissions that studied it advocate a high degree of regulatory intervention or prohibition. Surrogacy, particularly commercial surrogacy is frequently condemned. The main objection to surrogacy appears to be the potential for abuse in transferring the gestational function to a woman who is not a part of the intended nuclear family. Most commissions recommend frustrating contracts by deeming gestation to be the key to legal maternity. Only the OLRC is prepared to allow surrogacy subject to strict regulation and judicial pre-screening. The possibility of maintaining embryos indefinitely also triggered responses in all commissions that considered this issue. First they recommend a statutory hierarchy of control determined by biological contribution, then intended destination and finally physical custody. Second, they recommend statutory storage limits based mainly upon sociological, as opposed to medical, considerations.

Although the costs of many ARTs are not covered by provincial health insurance programs, aversion to private market forces was a common theme which was frequently used to justify

substantive moral limitations on personal autonomy.[162] Great concern was expressed over potential impacts of providing services within the private market setting. Some commissions felt that these concerns could be effectively controlled by regulation. Others felt that ARTs could only be ethically provided within the public system as private market forces would ultimately compromise human dignity. The commissions agreed that donation of reproductive materials should not be financially motivated. While ethical principles suggest that health resources must be used efficiently, it is not clear from the commissions that this principle precludes the provision of ARTs within a regulated private market.

Generally, the studies lack a robust, reasoned analysis of the function of legal instruments or the justification of regulation. Frequently the basis for significant intervention is described as self evident. Intervention is also based upon prior assumptions, arbitrary limitations,[163] perceptions of public opinion,[164]or proclamations about the inherent uniqueness of ARTs. An opportunity for more rational analysis of the existing legal landscape and the place of ART-related regulation in the landscape was lost by these convenient assumptions and limitations. Commissions also commonly claim that uniqueness precludes systematic, principle-based policy development. Some reports do attempt to articulate governing philosophies and principles, but there is often little substantive justification for specific recommendations and

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[162]Hardly surprising, given Canada's health care system. All expressed reservations, but were prepared to allow some commercialism to varying degrees, some pointed to commercialism in other areas of medicine.

[163] Commissions often limit discussion to these worthy groups (individuals who suffer from infertility and more recently those with genetic defects or disabilities), this creates a circular justification for placing ARTs within the politically significant category of medically required services.

[164]This is particularly troublesome given that the studies also emphasize the lack of relevant legal guidance; that the issues are personal; and, that there are profound ethical divisions over issues.

policies are often internally inconsistent.[165] Intervention is also unevenly justified or rejected based on the notions that participants will seek services from unregulated, unsafe or foreign sources, or that certain factors are not a consideration in natural reproduction, nor in the provision of other means of assisted reproduction. The reports fail to examine issues within the existing bedrock of provincial legislation and patient/physician relationships generally. They also fail to place legal regulation within the context of human reproduction generally or to account for existing regulation of sterilization and abortion. Finally, in areas where external controls are recommended, there is little consideration of the appropriate legal instrument of control or the appropriate external regulator.[166]

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[165]The unsystematic approach is epitomized in the RCNRT which openly acknowledges that the ethic of care model involves the inconsistent use of multiple principles.

[166]If external regulatory bodies are dominated by physicians they are illusionary and cannot reflect diverse perspectives.

CHAPTER FIVE: *International Legislative Responses*

Like Canada, many other nations have studied ARTs and legal reform. This chapter compares several foreign statutes to facilitate the analysis of the merits of different policy models in Chapter Six. For the most part, this review was limited to statutes enacted specifically to regulate ARTs.[1] Neither laws of more general application which might contain isolated relevant provisions,[2] nor delegated legislation such as regulations, codes of conduct and government policies were considered. The laws which were reviewed represent a cross-section of statutes enacted or proposed in the twenty years since the birth of Louise Brown in the United States,[3] the United Kingdom,[4] several Australian states,[5] Germany,[6] Austria,[7]

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[1]Wherever possible official versions of statutes were used; however, it was not possible obtain some official sources, particularly in nations where English is not an official language. Accordingly, some secondary sources were used to form the basis of comparison, see the notifications with respect to each of the jurisdictions regarding the sources used for comparison.

[2]The one exception to this was the United States. It was important to include the United States as it is the site of much ART activity and many well publicised legal conflicts. Further, America has a similar constitution to Canada, but a completely different health policy. ARTs are not highly regulated, ART related provisions are generally scattered throughout civil codes, criminal codes, professional laws, family laws, insurance laws and medical laws.

[3]The author reviewed several state laws and included five for comparison: California (*Cal. Penal Code* s. 367g (West 1996); *Cal. Civil Code* s.7005 (West 1996) *Cal. Health & Safety Code* s. 1374.55 (West 1996); *Cal. Insurance Code* ss. 110119.6 & 11512.28 (West 1996)), Virginia (Va. Code. Ann. 20-165-165;54.1-2971.1; 32.1-45.3 (Michie 1996)), New Hampshire (N.H. Rev. Stat. Ann. Ch. 168 B:10-B:31 (Michie 1998) and as originally proposed, reproduced in summary form (1990) 41 I.D.H.L 626), Louisiana (L.S.A. R.S.: Ss. 9:121 *et seq*; 9:2713; 40:1062.1 and Civil Code Art. 188 (West 1999.)), and Florida (Fla. Stat Ann. Ss. 381, 742 (West 1998 Supp.)). Federal laws were also considered: *Uniform Parentage Act*, U.L.A. s. 5 (West); *Uniform Status of Children of Assisted Conception Act*, U.L.A. 152 (Supp. 1998) and *The Fertility Clinic Success Rate and Certification Act of 1992* 42 U.S.C. ss 263a(1)-(4). For other comparisons of American State laws see: K. Byers, "Infertility and In Vitro Fertilization: A Growing Need for Consumer-Oriented Regulation on the In Vitro Fertilization Industry" (1997) 18 J. of Leg. Med. 265.

[4]*Human Fertilisation and Embryology Act*, 1990, c.37(hereafter *UK HFEA*);*Surrogacy Arrangements* Act 1985, c.49. See also D. Morgan & R. Lee, *Blackstone's Guide to the Human Fertilisation and Embryology Act 1990, Abortion & Embryo Research, The New Law* (London: Blackstone Press Ltd., 1991) and R. Stenger, "The Law and Assisted Reproduction in the United Kingdom and United States" (1994-5) 9 J. Of L. & Health 135.

[5]Five Australian states regulate surrogacy and all make such agreements void. Eight states assign parental status for the children of ARTs by statute. Only South Australia, Victoria and Western Australia have enacted ART laws dealing with other issues: the *In Vitro Fertilization (Restriction) Act, No. 27 of 1987;* Rep. and sub. by *Reproductive Technology Act*, No. 10 of 1988 [hereafter *South Australia*]; the *Human Reproductive Technology*

Spain,[8] France[9] and Denmark.[10] The enactments were examined to differentiate distinct policy models, and to decipher common types of laws and particular aspects of ART treatment transactions most likely to be the subject of legislative intervention. Statutory provisions respecting key elements of ARTs were evaluated including:

a) Explicit purposes and guiding principles or justifications for public involvement.
b) The identity, nature, composition and authority of statutory delegates.
c) Controls directly related to the treatment transaction, including: the level of patient, donor and provider autonomy with reference to criteria of access, consent, entitlement,

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Act, No 22 of 1991. This is a relatively lengthy act and it could only be accessed through *Halsbury's Laws of Australia*, vol. 18, looseleaf (Sydney: The Law Book Co., 1993) and B. Bennet, *Law And Medicine* (North Ryde: The Law Book Co., 1997) [hereafter *Western Australia*] so references to it are limited; *Infertility (Medical Procedures) Act 1984*, No. 10163 [hereafter *Victoria 1984*] and the *Infertility Treatment Act 1995*, No. 63 (as enacted in 1995, without subsequent amendments) [hereafter *Victoria 1995*].

[6]*Embryonenschutzgesetz, Bundegesetzblatt*, Off. Gaz. 1990 1: 2746-2748 (the *Embryo Protection Act*) as reproduced in summary form, (1991) 42:1 I.D.H.L. 60 reprinted from translation in (1990) 64 Bul. of Med. Ethics (9 December) 9-11. Also as discussed in E. Deutsche, "Assisted Procreation in German Law" in D. Evans, ed., *Creating the Child* (The Hague: Kluwer Law Int., 1996) 333 [hereafter *Germany*].

[7]*Act on Procreative Medicine*, 1992, No. 275 as reproduced in summary form, (1994) 44:2 I.D.H.L. 247. Also as discussed in E. Bernat & E. Vranes "The Austrian Act on Procreative Medicine: Scope, Impacts, and Inconsistencies" (1993) 10 J. Of Assisted Rep. & Genetics 449 and also in *Creating the Child, supra note* 6, 325 [hereafter *Austria*].

[8]*Law on Assisted Reproduction Procedures*, No 35 of 1988 (Bol. Off. del Estado, 24 November 1998, no 282, pp 33373-33378) as reproduced in summary form,(1989) 40:1 I.D.H.L. 82 reprinted from a translation of draft version prepared and made available by Max Planck Institute for Foreign and International Criminal Law. This bill was never enacted. Also as discussed in J. Martinez, " The Legal Situation of Assisted Reproduction in Spain" *Creating the Child, supra* note 6 at 287 (which also discusses *Donation and Utilisation of Embryos and Foetuses*, 1988, No. 42.

[9]France has enacted a series of bioethics laws dating back to the late 1980s which are dispersed throughout the codes and were not possible to obtain intact and in English. This comparison is based upon Law no 94-654, 29 July 1994 on *the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation and Prenatal Diagnosis* as reproduced in summary form: (1994) 45 I.D.H.L. 473. Other Secondary sources include: J. Lansac, "French Law Concerning Medically-Assisted Reproduction" (1996) 11 Hum. Rep. 1843; F. Busnelli, What Rules Should Govern Artificial Insemination?" in C. Massoni, ed., *A Legal Framework for Bioethics* (The Hague: Kluwer Law Int., 1998) 89; E. Pitrolo, "The Birds, The Bees, and the Deep Freeze: Is There International Consensus in the Debate over Assisted Reproductive Technologies?" (1996) 19 Houston. J. Of Int. L. 147 at 188- 191; and, C. Byk "French Assisted Reproduction Legislation" *Creating the Child, supra* note 6 at 347.

[10]Law No. 460 of 10 June 1997, *On Artificial Fertilization in Connection with Medical Treatment, Diagnosis and Research etc.* as reproduced in summary form: (1992) 43 I.D.H.L. and (1997) 48 I.D.H.L. 321 [hereafter *Denmark*].

financing and control over the use, storage and disposal of gametes and embryos.

d) Access to information and donor anonymity.
e) Supply controls, particularly, accreditation, reporting, and licensing.
f) Professional freedom, obligations and liabilities concerning treatment, collection and storage of materials, reporting obligations and disclosure.
g) The status of embryos and resultant children.
h) Prohibitions and enforcement mechanisms.

A. Statutory Trends, Patterns, Points of Consistency and Differentiation

ART specific laws have developed in different ways and at different paces responding to ongoing advances, notable litigation and other unique contextual factors. The actual enactment processes have followed many paths. In some jurisdictions proposed statutes have languished in legal limbo, caught between introduction and enactment for varied reasons. Elsewhere, well-publicised conflicts or scientific breakthroughs have been the catalysts for speedy passage of piecemeal laws. The birth of Louise Brown led to calls to ban IVF. In the mid eighties, concern over the spread of AIDs through ARTs, prompted statutory revisions which imposed HIV/AIDS screening of donor semen, cryopreservation of semen and waiting periods to account for the window of time within which donors might falsely test negative.[11] A single custody battle, involving Baby M[12] was the impetus for the promulgation of strict legislative controls and bans on surrogacy, particularly across the United States.[13] In France, a widow's successful battle with physicians reluctant to use her deceased husband's sperm

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[11]See Byers, *supra* note 3 at 298-297 for review of American state laws requiring HIV screening. The World Health Organization documented similar changes in the laws of many other nations including: Costa Rica (1989) 40 I.D.H.L. 378; Czechoslovakia (1990) 40 I.D.H.L. 48; and Venezuela (1994) 45 I.D.H.L 503.

[12]*In re Matter of Baby M* 537 A.2d 1227 (N.J. 1988). Other surrogacy cases gained notoriety elsewhere such as Baby Cotton in the UK, see generally J. McHale & M. Fox, *Health Care Law - Text and Materials* (London, Sweet & Maxwell, 1997) at 640-652; A. Capron, "Too Many Parents" (1998) 28:5 Hastings Center Rep. 22.

[13]See Congress of United States, Office of Technology Assessment, *Infertility: Medical and social Choices* (Washington D.C.: U.S. Printing Office, 1988) at 285-288 which outlines the state policies in the late 1980s.

for AI sparked strong reactions and ultimately a legal prohibition of posthumous insemination.[14] The untimely divorce of one couple and the death of another focused attention upon the problems associated with the perpetual maintenance of *ex corporal* embryos and resultant implications for family and estate matters.[15] The potential for conflicts amongst patients and providers were highlighted in conflicts over the custody and control of frozen embryos[16] and for erroneous fertilizations and implantations.[17] Infamous physicians in the United States who engaged in immoral practices and acted contrary to their patients' instructions spurred the promulgation of consumer protection laws and criminal laws prohibiting the unsanctioned use of reproductive materials.[18] More recent headlines are

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[14] *Parpalaix v. CECOS* (Tribunaux de Grande Instance) Creteil, Aug. 1, 1984, Gaz Pal. 11 cited and discussed in LRCC, *Medically Assisted Procreation Working Paper 65* (Ottawa, Minister of Supply & Services, 1992), at 40. A similar case occurred in the UK: "Widow Backed in Legal Fight for Husband's Sperm" (1996) 313 B. M. J. 898; D. Brahams, "Commentary: A Unique Case of Frozen Sperm Export?" (1997) 349 the Lancet 448. See also F. Peng, "Post-Mortem Insemination: Taking Sperm From the Dead" (1997) 5:3 Health L. Rev. 18.

[15] *Davis v. Davis*, 842 S.W. 2d 588 (Ten, 1992), cert denied *sub nom, Stowe v. Davis*, 507 U.S. 911 (1993) and *In Re Estates of Elsa and Mario Rios*, (May 1985), Los Angeles County, P680682, P680683 (Sup. Ct.). For other well known American cases see R. Bank & J. Merrick, *Human Reproduction, Emerging Technologies and Conflicting Rights* (Washington, D.C. Congressional Quarterly Press, 1995) and Pitrolo, *supra*, note 9.

[16] *York v. Jones*, 717 F. Supp. 421 (E.D. Va. 1989).

[17] J. Robertson, "The Case of the Switched Embryos" (1995) Hastings Centre Rep. 13.

[18] Dr. Cecil Jacobson, a reproductive specialist, was tried for using untested hormones to mimic pregnancy and for surreptitiously using his own sperm. His case is described in American Bar Association Section of Family Law, *Artificial Insemination and Legal Reality*, J. Tate (U.S.A.: American Bar Association, 1992). Drs. Asch, Balmaceda and Stone were convicted in California of using unapproved drugs, performing unauthorized research and using embryos without permission to facilitate pregnancies for profit see Byers, *supra* note 3 at 308 -312.

prompting calls for regulation regarding cloning,[19] contingency fees,[20] inducing multiple pregnancies, and genetic trait selection, particularly sex selection.

In some nations, ART laws are concentrated in single comprehensive enactments. In others, provisions are scattered throughout other generally applicable statutes which govern criminal activities, family and domestic relations, professional self-regulation, health and medical treatments and even insurance. Furthermore, governments that have enacted ART specific legislation have taken vastly different substantive approaches creating a confusing, frequently contradictory, body of laws. These laws reveal a profound diversity of legislative policy and ethical principles.

Diversity is not lessened by geographic proximity. Statutes vary amongst neighbouring jurisdictions and within nations. Across Europe some systems are extremely liberal, others are quite restrictive.[21] Legislative diversity is exemplified by legal provisions concerning embryonic experimentation. Experimentation constitutes criminal conduct in Germany.[22] In

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[19]See A. Bonnicksen, "Procreation by Cloning: Crafting Anticipatory Guidelines" (1997) 25 J. Of L. Med & Ethics 273 esp. at 278 - 279 which explains "cloning" procedures; American legislative initiatives; and, how legal language can unintentionally capture medical procedures. See also P. Kendall & R. Kotular, "Dr. Seed's Strange Love of Cloning" *Chicago Tribune* reprinted in *The Edmonton Journal*, (January 10, 1998) H2; P. Hopkins, "Bad Copies - How Popular Media Represent Cloning as an Ethical Problem" (1998) 28:2 Hastings Centre Rep. 6.

[20]See J. Robertson, "Professional Self-Regulation and Shared-Risk Programs for In Vitro Fertilization" (1997) 25 J. of L., Med. & Ethics 283; T. Murray, "Money-Back Guarantees for IVF: An Ethical Critique" (1997) 25 J. of L., Med. & Ethics 292.

[21] In Italy, the complete absence of legislation has created a totally permissive environment in which many controversial procedures are provided. In contrast, Austria and Germany have enacted extremely prohibitive laws. See also D. Evans & M. Evans, "Fertility, Infertility and the Human Embryo: Ethics, Law and Practice of Human Artificial Procreation" (1996) 2 Human Reproduction Update 208 outlining key elements of a final report to the European Commission on a project to coordinate national programs.

[22]"Europe is Divided on Embryo Regulations" (1996) 313 B.M.J. 512.

contrast, it is permitted up to the fourteenth day of development in the United Kingdom.[23] These diverse views have frustrated attempts at legal harmonization across Europe.[24]

Legislative diversity also exists amongst Australian and American states. Australia embraced ARTs, becoming a world leader in certain techniques. After much study, some state legislators deliberately chose not to enact ART specific laws, or to enact minimal provisions addressing only surrogacy and the legal status of resultant children. By contrast, other states enacted comprehensive, ART-specific regulatory systems. Victoria enacted the first and most comprehensive statute governing IVF.[25] Americans also embraced ARTs. Their use has spawned highly publicised litigation and calls for control; however, regulation remains sparse and scattered.[26] There is very little federal legislation concerning ARTs. *The Fertility Clinic Success Rate and Certification Act of 1992*[27] enhances consumer protection by enabling potential users to fairly compare competing providers. The *Uniform Parentage Act*[28] and the

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[23]If the research is for the purpose of advancing the treatment of infertility or contraception; detecting genetic abnormalities; increasing knowledge about congenital diseases, miscarriages; or, any other specified matter, *UK HFEA*, Sch. 2, s.3.

[24]L. Nielsen, "Legal Consensus and Divergence in Europe in the Area of Assisted Conception - Room for Harmonisation?" *Creating the Child, supra* note 6 at 304.

[25]For a critique of this act and others in general see K. Dawson & J. Leeton, "Viewpoint: The Regulation of Assisted Reproductive Technology in Australia: Issues and Solutions" (1995) 163 Med. J. of Australia 204.

[26]See Byers, *supra* note 3 at 289-299. Like other American health care issues, much of the debate has focussed upon financial impediments to access, see P. Neumann, "Should Health Insurance Cover IVF? Issues and Options" (1997) 22 J. of Health. Politics, Policy & L. 1214.

[27]*Supra*, note 3. Participation is voluntary.

[28]*Supra*, note 3.

Uniform Status of Children of Assisted Conception Act[29] deal with public records and the status of children produced through AI (if the procedure has been provided by physicians to married couples). Some states have adopted the uniform acts or variations of them. Other individual state laws vary widely, but generally are not as comprehensive as the laws of other nations.[30] This relative dearth of statutory materials is not surprising given the general legal tradition of individual freedoms, and the specific entrepreneurial and professional freedom traditionally enjoyed by physicians in America's private health care system. Failure or hesitation to enact statutes through the political process in America is also attributable to the controversial nature of ARTs and their association with reproductive rights, particularly with abortion.

B. Alternative Methods to Classify Statutes

Given this diversity, creating a framework for meaningful evaluation and comparison of this eclectic group of statutes presents a formidable challenge. A survey of the relevant literature reveals almost as many methods to categorize ART laws as laws themselves.[31] Most comprehensive statutory classification systems differentiate theoretical models based upon the intensity or purpose of government involvement. The OLRC advanced the most simple

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[29]*Supra*, note 3. For a review of states laws regarding the rights of artificially conceived children see V. Henry, "A Tale of Three Women: A Survey of the Rights and Responsibilities of Unmarried Woman Who Conceive by Alternative Insemination and a Model for Legislative Reform" (1993) 19 Am. J. of L. & Med. 285.

[30]ARTs laws are sparse even in Virginia and California where the most egregious professional abuses occurred.

[31]The variation in methods of analysis is due to the different frames of reference and the different subject areas under examination in the respective writings. Some address all aspects of ARTs, others address only specific procedures or issues such as surrogacy, parental status or trait selection. Further, reproductive issues can be viewed from many diverse perspectives: patient, prospective child, professional provider, public health, consumer, civil libertarian, feminist, and biological. See Busnelli, *supra* note 9.

framework of this genre: a dichotomous approach contrasting a purely private-ordering model (where the government simply enforces agreements made between private individuals), against a regulatory model (where the government, as protector of the public interest, sets coercive normative limitations upon the actions of private participants). Other authors use more finely calibrated categories. For example, some Canadian authors divide ART policies into a static model, a private ordering model and a slightly refined third category of state regulation involving either a punitive policy (where the state controls ARTs through penalties) or an inducement policy (where the law rewards individual compliance through legal affirmation of the parties' intentions provided they comply with proscribed conditions).[32] Similarly, in the late 1980s the United States Office of Technology Assessment sorted state policies into five models: static, private-ordering, inducement, regulatory and punitive.[33] The

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[32]R. Cook & B. Dickens, "Ethics and Human Values in Family Planning: Legal And Legislative Aspects" in Bankowski, Barzelatto & Capron eds., *Proceedings of the XXII Council for International Organization of Medical Sciences Conference on the Ethics and Human Values in Family Planning* (Geneva: CIOMS, 1989). See also B. Dickens, "News and Views, Reproductive Health Care Policies Around the World: Legislative Approaches to Assisted Reproduction" (1994) 11 J. Of Asst. Rep. & Genetics 327; A. Harvison Young, "Law Limits: Lessons From Yesterday, Strategies For Today," and P. Healy, "The Criminalization of New Reproductive and Genetic Technologies" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, U. of T., 1997).

[33]*Infertility: Medical And Social Choices*, *supra* note 13 Chapters. 13 & 14, esp. at 261-262 and 285-288. Under the static approach, dispute resolution is left largely to the judiciary who interpret the law in a conservative and chilling manner that emphasizes traditional family ties and minimizes the impact of ARTs whenever possible. While generally characterized by the absence of legislation, static jurisdictions may enact ART specific legislation such as laws deeming the birth mother to be the legal mother of a child to frustrate surrogacy agreements. Under the private ordering model, the law enforces the free will of individuals and their contractual agreements (in the absence of a pressing interest such as the endangerment of a child). Legislation is crafted to validate agreements about parental roles and to ensure that free will prevails. These laws often include consent as a prerequisite to parenthood. The judicial arm of government facilitates individual choice by interpreting the statutes consistent with the will of the individuals. These enactments do not address the lapses and gaps in contractual relationships amongst donors, recipients, surrogates, providers and intended parents. The inducement model is a regulatory system where the government validates agreements only if certain conditions are met. Failure to comply with set conditions results in invalidity and other penalties. Generally, providers are regulated in inducement models by licensing. The regulatory model involves the creation of an exclusive system or means to carry out an activity. This can be done by incorporating standards established by professional groups into directly enforceable laws. The punitive approach prohibits activities and voids ART related contracts.

laws of western Europe have been classified into four models: prohibitive, cautious regulatory, liberal regulatory and laissez-faire.[34]

In other classification systems, the overall level of regulatory intervention (affirmative, regulatory or prohibitive)[35] is only one factor for theoretical classification, the actual source of policy making authority and the degree to which ART laws deviate from other reproductive law policies are also considered. Choice of legal instrument is another less common criterion used to differentiate policy models.[36] Finally, statutes have also been compared by reference to the specific justification for intervention. Factors such as the timing of procedures (pre and post conception), the nature of the procedure (to identify genetic traits or to alter them), and the motivations of the parent (medical or nonmedical)[37] justify different degrees of intervention. This type of analysis can evaluate internal consistency and the means to achieve an overall policy objective. However, it does not necessarily address the more fundamental issue of the overall merits of a particular policy or the role of government as

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[34]Nielsen, *supra,* note 24 at 306-310. The author expands on these models in L. Nielsen, "From Bioethics to Biolaw" in *A Legal Framework for Bioethics, supra* note 9 at 39 using four models: Individual Control - Private Ordering; Professional Control and Ethical Councils - The Liberal Approach; Community Control - The Cautious Regulatory System; and Community Control - The Prohibitive System.

[35]Affirmative policies encourage the use of technology through direct funding, tax policy or by proscribing mandatory insurance coverage. Regulatory policies limit suppliers, set minimum standards and create dispute resolution processes which have the force of law. Prohibitive policies discourage the use of technology and limit individual rights and choices: Bank & Merrick, *supra* note 15 at 20-25.

[36]The specific legal vehicle used to carry out policy can reveal the true regulator and the true nature of the law.

[37]One author proposes a system of variable and mathematical pairs to inform and justify government intervention based on these three variables: O. Jones, " Reproductive Autonomy and Evolutional Biology: A Regulatory Framework for Trait-Selection Technologies" (1993) 19 Am. J. of L. & Med. 185.

protector, provider, regulator, or payor.[38]

C. Emergent Legal Models

As will be seen below, the models proposed above inadequately capture the nature of the actual enactments. While some acts can be slotted into overall categories, not all enactments fit neatly into the proposed policy pigeon holes. Some laws are incomplete. Others are inconsistent. When compared on the basis of the actual provisions, three basic models do emerge upon a detailed review of these statutes: remedial/laissez faire, penal and regulatory.[39]

1. Laissez Faire*/ Remedial Models*

Of the three basic models, remedial models have the greatest potential to affirm the individual will of ART participants and come the closest to the *laissez faire* approach described by the OLRC and the OTA in Chapter Four.[40] Remedial models do not directly regulate patient/physician relationships. These laws explicitly address only residual issues, such as the legal status of resultant children.[41] Statutory intervention is triggered by the existence of live progeny of ARTs, rather than by the use of ARTs. Remedial family laws are generally

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[38]But note *ibid.* at 221 where the author argues that regulation should only be justified to avoid clearly and significantly damaging behaviour.

[39]See R. Swidler, "Medical Innovations and Ethics: A State Government Perspective" (1994) 57 Albany L. R. 655.

[40]It must be remembered that several legal layers (including generally applicable codes, statutes and common law precedents) apply to ARTs regardless of the existence of specific legislation. So a *laissez faire* model really leaves control to individual patients and providers in the self-regulated medical *millieu*.

[41]This is the very issue that Canadian law reform projects consider imperative, the same issue that Canadian courts have dealt with absent special provisions, see generally chapters 3 and 4 above.

designed to give children of ARTs the same rights as their naturally conceived counterparts.[42] These laws balance the rights and obligations of existing legal persons to create situations favouring the interests of the resultant children. These laws specify who will be entitled to parental status and subject to parental obligation. Generally, birth triggers legal maternity (making surrogates and gestating mothers legal mothers), while, fatherhood (absent a biological nexus) turns upon spousal relationships with the legal mother or upon consent. These laws mix the private-ordering and static models, they affirm the party's intentions by regularizing the social situation for most, but not all, ARTs. Often the statutory schemes apply only if certain preconditions have been met.[43] A few Canadian provinces, several American States and New South Wales have adopted this approach.[44]

2. Criminal Models

Criminal models start from the negative perspective that ARTs are suspect. These models are characterized by relatively succinct statutes that define the situations in which specific exceptional ARTs may occur. Criminal statutes are distinguishable from other laws as they

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[42]With the exception of children conceived posthumously who frequently receive inferior succession rights. Often their entitlement is conditional upon being specifically contemplated in their father's wills.

[43]Often children's rights are triggered only when ARTs are provided by licensed physicians, when the parents are married or when spousal consent has been obtained.

[44]After lengthy study, legislators in New South Wales chose to leave legal and ethical controls to the existing self-regulatory mechanisms governing the medical profession and to other *defacto* controls. In the mid 1980s, the legislature enacted a minimalist and simple artificial conception statute setting out rules for determining the parentage: *Artificial Conception Act, 1984*, No. 3, s. 5 and 6. Together with the *Children (Equality of Status) Act 1976*, No. 97, it ensured that a consenting intended father would be the legal father, while a sperm donor would never be a legal father. This scheme was replaced in 1996 with new more detailed provisions contained within a family law statute applicable to all children *(Status of Children Act 1996*, No. 76). The new provisions set out specific rebuttable and irrebuttable presumptions to determine the legal parents of children conceived artificially in heterosexual relationships based upon consent and the locus of gestation, ss.14-17.

always include generally applicable legal prohibitions enacted to preserve a public purpose. The prohibitions are enforced through penalties in the form of a loss of privilege, a fine or a period of incarceration. These laws have significant symbolic effect and can severely limit professional freedom and patient or donor autonomy.

A small minority of the surveyed jurisdictions,[45] including Germany[46] and Canada (if Bill C-47 is enacted) have adopted penal models. The German statute was enacted in 1990 to protect human embryos.[47] It criminalizes several practices that are considered ethical and commonly engaged in countries which have adopted more permissive regulatory or remedial models. In Germany, ARTs are contingent upon a genetic maternal nexus. Embryos may only be created

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[45]South Australia enacted a penal statute in 1988 for seven months as an interim control measure, it was replaced as planned with a regulatory model. The act made practising IVF or any related uses of human ova a summary offence subject to a $10,000 fine unless performed in one of five specified facilities. Other nations use severe regulatory models which include penal sanctions. These laws are broader than mere penal enactments. For example, in Austria the ART specific legislation is quite succinct and includes fines and imprisonment. But this law is not purely criminal, it was enacted to answer all possible legal questions: to prohibit unacceptable practices, to regulate lawful services and to define the status and legal relationships linking participants. As in Germany, professionals in breach of this law are also liable under their disciplinary codes.

[46]See Deutsch, *supra* note 6 at 333-335 who notes that the *Embryronenschutzgestz* is not the only law impacting ARTs. It is supplemented by harsh professional standards enacted in 1985 that are legally binding and enforceable by independent professional courts. Laws governing adoption also prevent commercialised surrogacy. The law also includes provisions about mandatory disclosure and documenting consent about the medical and psychological aspects including the chances of success, complications and cost. The social security code provides that ARTs are covered under the public health insurance system if:

a) the physician considers ART to be necessary;
b) the procedure is likely to bring about pregnancy (after four attempts chances are considered poor);
c) the parents are married;
d) ART is homologous and uses materials from the intended parents; and,
e) the parents have been instructed about medical and psychological aspects by a physician other than their attending physician.

Special exemptions may be sought for non-spousal sperm and for cohabitants.

[47]Embryos include human egg cells, fertilized and capable of development from fusion of nuclei and each totipotent cell capable in the presence of other necessary conditions of dividing and developing into an individual, s.8.

by physicians and only for purposes of assisted reproduction.[48] Only three embryos may be created per treatment cycle, and the act specifies that ova may be implanted only in the woman who supplied them originally. Embryo donation and surrogacy are outlawed. German patients cannot use embryos that they are not genetically connected to and they cannot employ the services of a surrogate. Harsh punishments apply to genetic alteration, cloning, creating chimeras and cross-species implantation. Oddly, a less severe penalty applies to sex selection. The act targets providers of services rather than patients. Providers are subject to sanctions of up to one, three or five years of imprisonment and fines for violations of the act.[49]

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[48] Section 9 provides that only physicians may carry out artificial fertilization, embryo transfers or preservation of human embryos; s.11 makes it a criminal offence to provide ARTs without a professional designation.

[49] The hierarchy of specific offences and their potential application and potential sanctions include:
a) Crimes subject to fine or imprisonment for up to 1 year:
- s.11 practising ARTs without being a physician up to 1 year or fine;*
- s. 3 preconception sex selection or attempts to select sex unless selection of sperm is made by physician to prevent Ducennne type muscular dystrophy or a sex-linked hereditary disease of similar severity and if the disease is recognized by the proper authority.

b) Crimes subject to fines and imprisonment for up to 3 years
- s.1 transferring unfertilised egg produced by another woman;*
- s.1 fertilizing eggs for any purpose other than bringing about a pregnancy of the woman who provided the eggs*;
- s.1 transferring more than three embryos into a woman in one cycle;
- s.1 attempting gamete transfers with more than three egg cells in one cycle;
- s.1 trying to fertilize more egg cells from a woman than may be transferred to her within one cycle;
- s.1 removing an embryo from a women before implantation to transfer it into other woman or using it for a purpose that is not conducive to its preservation;*
- s.1 attempting ARTs or transferring a human embryo into a woman who is prepared to give up her child permanently after birth;*
- s.2 transferring or attempting to transfer an embryo for any purpose other than its preservation and for pregnancy;
- s.4 attempting any ARTs without consent of egg and sperm sources;
- trying to transfer an embryo into a woman without consent; and,
- knowingly fertilizing an egg with sperm of a man who has died*

c) Crimes subject to fines or imprisonment for up to 5 years:
- s. 5 artificially altering or attempting to alter genetic information in a human germline cell or using a human germ cell that is modified (subject to some exceptions if there is no possibility the embryo will be used for fertilization)
- s.6 cloning and using clones in conjunction with ARTs ;
- s.7 creating or attempting to create chimeras or hybrids or transferring them into a woman or an animal; and
- s.7 transferring a human embryo into an animal.

The act also includes a conscience clause; s.10 provides that no person is required to perform artificial fertilization, transfer human embryos into a woman or preserve any sperm, egg or embryo. The penal provisions do not apply to other forms of reproductive assistance nor to the use of fertility drugs which can result in the creation of many more than three embryos per treatment cycle.

3. Regulatory Models

Between the extreme penal and remedial models lies the diverse, catchall regulatory category where law is used to meet several objectives. Regulatory laws typically focus upon the provision of specific services, rights of access, the *ex corporal* use of human reproductive materials and mediating relationships amongst the genetic donors, patients and service providers. The statutes tend to either provide many details,[50] or to simply sketch out broad policy guidelines, leaving detailed rule making authority to other bodies and other legal instruments. Some regulatory statutes can be further divided based upon the intensity and purpose of government intervention in patient/physician relationships and the nature of the legal instrument chosen to carry out the objective of the legislation. However, most enactments tend to be compartmentalized. They address discrete issues unevenly, rather than adopting a uniform, considered philosophical approach. Accordingly, it is more instructive to compare the statutory provisions concerning the key ART elements outlined above than

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*Denotes crimes that do not apply to donors, recipient women, or intended parent as the case may be.

[50]This detailed approach is epitomised in the Australian state of Victoria. Victoria enacted the first IVF specific law in 1984, a statue 23 pages in length. In 1995 it was replaced by a new more comprehensive act 151 pages in length. Detailed regulations were enacted under both statutes.

to force them into more theoretically refined, but ill-fitting categories.

a. Purposes of Statutory Enactment

The purposes, guiding principles and justifications for government involvement are explicit in some statutes, but can only be inferred in others. Many acts include nonmedical or social goals. Commonly they are enacted to ensure that only "worthy" patients may access ARTs[51] or to ensure that human embryos are created only to facilitate human reproduction.[52] Some acts espouse multiple purposes.[53] All the statutory objectives involve four basic themes. The first is to protect human life, particularly human embryos. The second is to regulate and control practices involving human embryos, medical procedures and genetic technology.[54] The third is to permit assisted procreation conditionally upon medical need (such as the diagnosis

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[51]The precise meaning of "worthy" varied. Some statutes equate worthiness to marriage, or extended periods of cohabitation. In others it is equated to parenting ability, sexual orientation or proven medical or genetic need.

[52]E.g. *UK HFEA; Austria; Spain*, s.3

[53]The 1995 Victoria statute is the most explicit and multifaceted, s.1. It was enacted to

- regulate the use of fertilisation procedures, access to information about treatment procedures, research using human gametes, zygotes and embryos;
- promote research into the incidence and causes of infertility;
- make provisions regarding surrogacy agreements; and,
- establish the Infertility Treatment Authority and the Standing Review and Advisory Committee on Infertility.

Then the act specifies guiding principles in descending order of importance, s.5:

- the welfare and interests of any person born or to be born through treatment procedures are paramount;
- human life should be preserved and protected;
- the interests of the family should be considered; and,
- infertile couples should be assisted in fulfilling their desire to have children.

The 1984 Victoria version was also quite explicit, setting out in its title that it is an act to regulate certain procedures for the alleviation of infertility or to assist conception and to prohibit surrogate motherhood and for other purposes. It also provides that in crafting regulations, authorities must remember that childless couples should be assisted in fulfilling their desire to have children and that highest regard is given to the principle that human life shall be preserved, s.29.

[54]This traditional regulatory function is described by Swidler, *supra* note 39 at 657-658.

of human sterility or the detection of serious hereditary or genetic disease or defect).[55] The fourth is to limit access to available technology based upon nonmedical reasons.[56]

b. Parameters of Statutory Coverage

The sphere of regulated activity varies from one enactment to another. Some acts are narrow, covering only specified procedures such as IVF, AI or surrogacy. Some acts are wide, covering all reproduction techniques outside the natural process, or all procedures designed to result in the impregnation of a woman. Despite seemingly inclusive language, the latter types of statutes do not appear to govern more traditional forms of assisted procreation.[57] A few acts also apply to genetic research and diagnostic techniques for the detection of serious defects or pathology in human embryos.

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[55]In Austria the statute was enacted to make ARTs available only if all other possible and reasonable treatments for inducing a pregnancy by means of sexual intercourse have failed and will fail, s.2. In Spain s. 1 provides that the law is to regulate AI, IVF, ET and GIFT when they are scientifically and clinically indicated and performed in authorized and accredited health and scientific centres by specialized teams. Section 2 qualifies this providing that general principles can be employed only if the proposed procedure has a reasonable chance for success and does not pose a serious hazard for the health of the mother and any resultant descendants.

[56]According to its Statement of Purpose, New Hampshire enacted the *Surrogacy Act*, Ch.168-B (which covers other ARTs) to recognise that surrogacy is practised, creates complex and unsettled legal issues and that ignoring or banning it would lead to unregulated arrangements. The law establishes consistent state standards and procedural safeguards to protect all parties, and to determine the legal status of children born as a result of the arrangements. Nonmedical considerations were specified, the act ensured that surrogacy arrangements were only utilized by married couples and only when necessary and that all participants were physically, emotionally and mentally qualified and able to fully support the resulting child.

France, Art L-152-2 provides that the law aims to respond to the wishes for parenthood of married or common law heterosexual couples that have been medically diagnosed as infertile or with a great risk of genetic disease or HIV transmission. This excludes "social demands" and precludes singles, nonmarried couples with under 2 years of cohabitation and homosexuals. Byk, *supra* note 9 and Lansac, *supra* note 9 agree that the intention is to ensure that children are born to stable, well-informed couple.

[57]Such as the prescription of fertility drugs or surgical techniques to restore "normal" reproductive function through the reversal of tubal ligation or clearance of blocked fallopian tubes.

c. Statutory Delegates and Policy Formulators

The need for administrative authorities to supplement and administer the legislation is recognized in all the acts. The very purpose of South Australia's skeletal legislation is to constitute an administrative board to create a code of conduct to govern ARTs (subject to the few absolute parameters listed in the act). Each jurisdiction adopted a slightly different approach regarding the identity, composition and powers of its administrative authority. Some acts grant authority to existing government authorities such as the Lieutenant Governor in Council, the responsible minister, the Administrative Appeals Tribunals, the courts, specialised health care bodies, professional authorities, or health departments.[58] Other enactments create new tribunals to deal exclusively with ARTs, or they divide administrative control between newly constituted and existing authorities. The statutes which created new authorities often specify characteristics about the composition of those authorities.[59] All novel authorities are governed by appointed boards.[60] Some statutes stress the need for medical expertise on these boards. Others also recognize the need for a multidisciplinary representation, diversity and equal representation by men and women. The powers delegated to these authorities varies. Some have been created to gather information and perform purely

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[58] *New Hampshire*, B:31 delegates rule making authority to the Department of Health and Public Services. *Denmark*, ss. 17, 20, 21, and 27 delegate rule making and approval authority to the Minister of Health, National Board of Health and Scientific Ethics Committees.

[59] South Australian created the Council on Reproductive Technology, members are to have expertise, reflect relevant disciplines, the general community and draw equally from both sexes, s.5. France created the National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis, its members were physicians with expertise in reproduction chosen by representative organizations. The UK created the Human Fertilisation and Embryology Authority, Sch. 1 to *UK HFEA* requires that the chair, deputy chair and additional members be appointed at the discretion of the Secretary of State taking account of the desirability to have views of both men and women. One third to one half of the members must be registered medical practitioners, or concerned with the relevant procedures or involved in commissioning or funding research in the field, Sch.1, s.4.

[60] E.g. *Victoria 1995*, s. 123(1); *UK HFEA*, s. 5, Sch. 1, s.4; *South Australia*, s.6.

advisory functions. Others are constituted to assume legislative, executive and quasi judicial functions including: promulgating direct treatment limits and standards of practice,[61] monitoring compliance, licensing and suspension.[62] Agencies are frequently required to report on their activities and findings to patients, the public or the responsible ministers.[63] Only one statute granted a statutory immunity for the administrative board governing ARTs.[64]

d. Statutory Control of Demand: Patient Access, Informed Consent and Autonomy

Access is addressed in all statutes. No acts recognize an unqualified right of access to ARTs. Some jurisdictions do not restrict access to ARTs based upon personal characteristics of potential users.[65] Others, in accordance with their medical and social purposes, limit ARTs

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[61]South Australia empowered the Council of Reproductive Technology (SARCT) to establish a code of ethical practice and licensing conditions subject to certain minimum standards outlined in the statute; to research the social consequences of ARTs and infertility; to disseminate information; to advise the minister on licensing conditions; to collaborate with other similar bodies in Australia; and, to grant, suspend and cancel licenses (ss.10, 11, 14, and 15). The SARCT acts in an advisory capacity to the main health authority which is authorized to license providers of reproductive services. Power is divided with respect to some licenses and decisions of the SARCT are not reviewable while those of the general health commission are appealable. Governor can also make regulations regarding consent, licenses and reporting and can impose penalties or fines of up to $2,000.

[62]The Human Fertilisation and Embryology Authority was constituted to set standards and to control the provision of services involving excorporal human fertilization, ss. 5-10. A subcommittee issues, reviews and revokes licenses subject to an appeal to the whole board, s.16. Then an appeal to the courts is permitted on questions of law alone. HEFA must keep government and public abreast of its activities by providing advise and annual reports to Secretary of State who must lay them before Parliament, *UK HFEA*, s.7. See also the Standing Review and Advisory Committee on Infertility which was established to provide advice and to approve experimentation (Victoria 1984, s.29) It has now assumed many more administrative and licensing duties under the new act, including the obligation to advise the Minister of any contraventions of the act (*Victoria 1995*, s. 122).

[63]The respective responsible ministers are often required to place the reports before the relevant legislature annually. E.g. in South Australia s. 12 requires the Council to report to the minister annually about use of ARTs through the year, significant developments in ARTs over year, any discernible social trends attributable to ARTs and any other matters, then Minister has 6 sitting days to lay copies of the report before Parliament. See also *France*, Art. L.184-2, 3 and 4).

[64]*Victoria 1995*, s.132.

[65]Spain actually affirms that every woman is entitled to access ARTs if she is over 18, fully competent and has given free and express consent, s.2. Older women must be informed of risks and or risks resulting from unsuitable age. The UK's permissive regulatory system does not include explicit access restrictions, although, s.13 (5)

to "worthy recipients." The parameters of worthiness vary and are based on medical and non-medical considerations. Commonly access is predicated upon a diagnosis of infertility or a medical opinion that natural reproduction is not possible.[66] Many jurisdictions, but not all,[67] also allow access if it is established that sexual reproduction is highly likely to transmit a serious genetic disease or defect.[68] Fewer statutes include an additional requirement that intended recipients exhaust all other alternatives and that the proposed ARTs have a high likelihood of success. Other clearly nonmedical restrictions are either explicit or implicit. Typical access criteria include: a legally recognized marriage of any duration,[69] a heterosexual marriage-like relationship of a specified duration[70] or spousal consent.[71] Other statutes go further and require a third party (counsellor, physician or judge) to assess the prospective parents and affirm their parenting ability. Judicial approval is a prerequisite to embryo

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provides that the need for a father must be considered in the provision of ARTs.

[66]The New Hampshire law requires that women be medically evaluated and found to be medically acceptable in accordance with state set policies prior to receiving AI or IVF, ss. B:12-B:13. In France medical need and judicial preapproval are required before couples can receive a donation of both gametes, Art. L. 152-6.

[67]Austria provides that medically assisted procreation may be provided to married women and women who are in a common law heterosexual relationship of any duration that approximates to matrimony and only if given the current state of science and experience all other possible and reasonable treatments to achieve pregnancy by sexual intercourse have failed and will fail, s.2.

[68]South Australia provides that a medical diagnosis is required for IVF and for the use of donated materials in addition to confirmation of medical need for the proposed service, ss.10-13. Similarly the Victoria laws both limit access to married couples who provide written consent and are able to obtain confirmation from a physician that they are unlikely to become pregnant without ARTs, or that sexual reproduction might result in the transmission of a genetic abnormality or disease (*Victoria 1984*, ss. 10-13; *Victoria 1995*, s. 8).

[69]Frequently marriage is implied by the use of terms such as wife and by references to spousal consent, *France*, Art. L.152-2. *UK HFEA* does not require marriage but dictates that services may not be provided unless account is taken of the well being of any child who may be born, including the need for a father. Account must also be taken of the welfare of any other child that may be affected by the birth, s.13(5).

[70]*France*, L152-2 (two years): *South Australia*, s. 13 (five years); *Denmark*, s.3 (no time limit) .

[71]Spain makes a unique exception to the requirement of spousal consent for legally separated couples, s. 6(3).

donation in France and to surrogacy in New Hampshire. Some statutes add that the couple must be alive at the time of the procedure.[72] A few acts include explicit age requirements.[73] The acts do not generally address one key determinant of access, financial responsibility for ARTs. Presumably, as in Canada and Germany, this element is left to other health care and private insurance laws.[74]

The provision of ARTs is predicated upon informed consent. All acts that mention consent affirm the value of full pretreatment disclosure. These statutes often prescribe standardized consent forms and dictate the minimum elements of disclosure. The disclosure process is sometimes supplemented by mandatory pretreatment counselling provided by accredited counsellors or attending physicians about prescribed matters.[75] Austrian law, for example, mandates in depth pretreatment discussion and counselling for the recipient and her partner (unless the partner declines) about the proposed procedure and the risks for the woman and the desired child. Additional counselling before a court or notary regarding the legal

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[72]In France a ban on posthumous donation was specifically added to the legislation in response to a well publicised case in which a French widow successfully applied to the courts to use stored sperm of her deceased husband: *Parpalaix, supra* note 14. See also *Denmark*, s. 15, 19.

[73]*France*, Art. 152-2 requires couples be of procreative age. *Denmark*, s.6 prohibits ARTs if the woman to give birth is over 45. *Western Australia*, s.23(d), provides that age must not be the sole reason for infertility.

[74]See the discussion about German regulation above and the discussion on reimbursement in Canadian system in Chapter 3 above. The insurance laws in some American states either mandate ART coverage or exclude it. Texas covers some costs and California expressly excludes them. For a review of the laws in other American states see Neumann, *supra* note 26. If coverage is extended, it is often conditional upon many of the access conditions found in regulatory models

[75]Victoria enacted detailed provisions on consent, both acts specify information to be disclosed and the forms to be used by accredited counsellors (*Victoria 1984*, ss. 10-12, 18 and 19, *Victoria 1995*, ss. 10, 11). Virginia enacted detailed disclosure requirements, regarding the success rates and screening protocols, s. 54.1-2971.1.

consequences is required if donated materials are involved.[76] Most statutes specify that consent may be conditional or limited and may be revoked up to the point in time that the materials are actually used.[77] The enactments encourage an anticipatory approach, requiring patients to consider the implications of the existence of extra corporal reproductive materials, particularly embryos by addressing future uses of reproductive materials. As part of the consent process, the acts frequently force patients to document their instructions about the future use of reproductive materials and embryos. To ensure that plenary discussions and the consent processes as mandated in the acts actually occur, a statutory duty is frequently imposed on physicians and others to document consent and to retain records of consent.

e. Statutory Control of Donors: Screening, Liability, Participation and Identity

Statutory provisions concerning donors address screening, consent, disclosure, legal rights, the flow of information amongst donors, recipients and their families and the special statutory liability of donors.

Most statutes require that potential donors be medically evaluated by physicians.[78] Many also require testing for specific diseases, particularly AIDs. To ensure adequate testing occurs, the

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[76]E.g. *France*, Art. L. 152-10. *Victoria 1995* also requires detailed disclosure of legal rights of participants and interested parties including the offspring to access information, ss. 10,11, 21.

[77]It is important to note that patients often are contemporaneously donors. In such cases consent deals with two issues - consent to receive treatment and consent to surrender physical custody of reproductive materials. These statutes do not fully address this dual role or specify that treatment should not be conditional upon donation of "spare materials." Donor consent is addressed separately below.

[78]*New Hampshire*, B:10, B:14.

use of fresh sperm is banned and quarantine periods are imposed.[79] California law requires such testing, but allows patients to waive testing for known donors.[80] Some laws also include nonmedical screening criteria. In France, donors must be married with children and their spouses must consent to the donation. In Spain, donors must be adults and medical teams are responsible for selecting donors which match the phenotypic and immunological characteristics of the recipient and maximise compatibility with her and her family environment.[81] Donor records are also required to ensure that the prescribed maximum number of offspring per donor is not exceeded.[82] Some statutes make donors legally accountable for providing materially false or misleading statements about themselves, unless they believed, on reasonable grounds, that the information was true.[83] Those who donate knowing that they have and may transmit HIV are criminally accountable in Florida.

Consent to donation is addressed less frequently than consent to treatment. This is unfortunate as recipients are often also donors.[84] The statutes that do address donor consent include provisions comparable to those governing consent of recipients regarding counselling,

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[79]*France*, Art. L 673-3; *Spain*, s.5(6). Florida requires HIV testing, providers who neglect to test are guilty of a misdemeanour offence, s. 381.0041(11).

[80]*California Health and Safety Code*, s. 1644.5. requires testing for HIV, viral hepatitis, human T lymphotrophic virus-1 and syphilis. See also *Virginia*, s. 32.1 - 45.3 and *Louisiana* , s. 40: 1062.1 which lists mandatory tests and then exempts spouses from testing and includes a $2,000 fine and civil liability.

[81]*Spain*, ss. 5(6),6(5); *Victoria 1984*, s.25; *Victoria 1995*, ss. 41,42 ban the use of gametes obtained from foetuses or children.

[82]In Spain the National Registry ensures no more than six children are conceived from the same donor, s. 5(7). In France the maximum is five, Art. L. 673-4.

[83]E.g. *Victoria 1984*, s. 27, *Victoria 1995*, s.58.

[84]Some laws account for the fact that donors may also be recipients: *UK HFEA*, Sch. 3; *Spain*, s.5(2), (8). In Denmark ova can only be obtained during IVF treatment so donors are always also patients, s.14.

spousal consent and documentation.[85] Some statutes also require that donors receive detailed information about proposed uses and document their consent regarding those uses. Consent usually may be withdrawn or revoked until fertilization, insertion or other use.[86] In Spain, donors can revoke consent and reclaim their unused gametes if they need them later due to personal sterility.[87] Providers must maintain consent records and are accountable for failure to obtain proper consent or maintain proper records.[88]

Commercial donation is certainly legal in some jurisdictions, but the surveyed statutes prohibit donation for profit and commercial transactions in general. Under the Spanish statute, donations of gametes and preembryos are characterized as gratuitous, formal and secret contracts made between the donor and the treatment centre.[89] Sales of ova and embryos are prohibited in Louisiana.[90] France and Victoria allow the reimbursement of costs only.[91] Florida allows reasonable compensation directly related to the donation of gametes and preembryos.[92]

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[85] *UK HFEA*, Sch. 3 prescribes the same consent forms for recipients and donors providing gametes and embryos.

[86] *France*, Art. L673-2; *UK HFEA*, Sch. 3, s.4; *Spain*, s. 9(4); *Victoria 1984*, s. 15; *Victoria 1995*, s. 37.

[87] *Spain*, s 5(2) if they are still available.

[88] *Victoria 1995*, ss. 14, 36, 62-70; *Spain*, s. 5. In California failure can be a disciplinable offence and a criminal offence if repeated, *Business and Professions Code*, s.367g.

[89] *Spain*, s.5.

[90] *Louisiana*, s 3.122; *Denmark*, s.12 also prohibits the sale of ova..

[91] *France*, Art. L665-13 and *Victoria 1995*, s. 57 respectively. In France intermediaries must be nonprofit, Art. L. 673-5.

[92] *Florida*, s.742.14.

Most acts contain provisions governing the circulation of information amongst participants[93] and follow one of two basic philosophies: a completely anonymous system where donation is an act of total factual and legal severance; or a more open system, based upon the right of children to know their biological origins.[94] These opposing theories are reflected in laws about designated donation and disclosure of donor identity. France adopts a secretive system. Designated donation and disclosure are not permitted.[95] In Spain, donation must be anonymous and the particulars of identity must be kept in strict secrecy in coded files stored at the National Register of donors. Resultant children are entitled to obtain general information concerning the donors, excluding identity. Donor identity may only be disclosed in exceptional cases if there is a verified danger to the life of the child and if disclosure is indispensable to avert the danger or to attain a proven legal objective.[96] By contrast, more open systems contemplate a dual track: donor anonymity is preserved unless donors have consented to disclosure in the prescribed manner. Originally Victoria allowed open arrangements, explicitly authorizing designation of recipients and donors.[97] Under Victoria's 1995 statute, donors may be identified upon written request if all parties, including the donor,

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[93]*UK HFEA*, s.31-35. These sections were relaxed in 1992 when the original provisions proved impractical.

[94]Anonymity remains very contentious, see K. Daniels & O. Lalos, "The Swedish Insemination Act and the Availability of Donors" (1995) 10 Human Reproduction 1871; F. Shenfield & S. Steele, "What are the Effects of Anonymity and Secrecy on the Welfare of the Child in Gamete Donation?" (1997) 10 Human Reproduction 392.

[95]*France*, L 673-6, 7 and Art. L. 152-5. *Denmark*, s.14 prohibits designation, the act does not address subsequent disclosure. In South Australia unauthorized disclosure of confidential information or donor identity is punishable by a $5,000 fine or imprisonment for up to six months, s.18.

[96]*Spain*, s. 5(5).

[97]*Victoria 1984*, s. 16.Donors could receive information about their materials including how they were used and whether a pregnancy or birth occurred through designated officers of approved hospitals, s. 20. See also *Victoria 1995*, ss. 73, 76-78.

have been counselled and agreed.[98]

f. Supply Side Controls: Provider Licensing, Accreditation and Other Obligations

Supply side controls are most commonly achieved through licensing of the people and facilities providing ARTs.[99] Some acts simply constitute an authority with wide discretion to create licensing schemes, others specify mandatory license terms. Licences are of limited duration (usually three or five years) and are revokable by administrative authority or judicial order for breach of statute or of licence conditions. Decisions of these authorities are usually final (subject to judicial review) and statutory appeals are quite limited.

Statutes often specify that ARTs may only be supplied by licensed physicians.[100] Some acts require additional qualifications providing that certain procedures can only be supplied by specially accredited physicians[101] or "fit and properly trained" physicians working in specially approved locations or facilities.[102] Other acts require physicians and facilities providing ARTs to follow preexisting professional guidelines.[103] Other professionals such as councillors and

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[98]*Victoria* 1995, ss. 18, 19 and 75.

[99]*UK, HFEA* provides a typical example. Much of the act is devoted to establishing an administrative licensing body. The statute contemplates three types of licenses: treatment services, gamete and embryo storage and research. Schedule 2 outlines mandatory license terms and limits. Regulated activities can only occur on licensed premises and only under the supervision of a "person responsible." A licensing committee is empowered to issue, monitor and revoke licenses, some committee decisions are final while others may be appealed to the Courts.

[100]E.g. *Victoria 1984*, s. 17; *Louisiana*, s.3.128; *Denmark*, s.18.

[101]*South Australia*, s.13.

[102]*Austria*, s. 4; *France*, Art. L673-5; *South Australia*, s. 13; *Victoria 1984*, s. 7; *Victoria 1995*, ss. 93-120.

[103] E.g. *Louisiana*, s. 3.128 states that facilities must meet the standards of the American Fertility Society and American College of Obstetricians and Gynaecologists. New Hampshire has a similar requirement.

other corporate officers are also required to obtain special licenses.[104] The more detailed enactments create special positions or designated officers to be responsible for compliance and cooperation with authorities auditing compliance.

Regulatory statutes generally require licensees to comply with all statutory and licensing provisions.[105] In addition, the acts create novel duties to ensure that informed consent has been obtained and that the procedures they propose have been approved by the patients and donors of reproductive materials. The obligations to counsel patients and to obtain and document informed consent are placed on attending physicians, designated officers within facilities or the facilities themselves. Further, the statutes frequently control the flow of information by creating unique obligations concerning the collection, maintenance and dissemination of records.[106] These obligations are imposed upon attending fertility specialists, physicians who deliver children known to have been produced by ARTs, hospitals, governmental agencies or specialized authorities. Based on all the statutes, the information most likely to be collected and retained includes: pretreatment health of recipients and donors, amounts paid to donors, details of consent and disclosure documentation, particulars of the use and destruction of embryos and gametes (particularly the mixing of gametes), procedures provided, outcomes of procedures, and the subsequent health of neonates and mothers. Some

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[104]E.g. *Victoria 1984*, s. 7; *Austria*, s. 4 provides that counsellors must have special ministerial licenses.

[105]E.g. *South Australia*, s.13 provides that all ART licensees are subject to the condition that they follow the Commission about specified procedures, material sources and provide ARTs only to acceptable applicants (defined as couples who are married or live common law for five years or more; and are either infertile or at risk of transmitting genetic defects through natural conception).

[106]E.g. *South Australia*, s.13(3)(d); *Spain*, s. 19. See the discussion of disclosure and donor identity above.

statutes also require providers to supply standardized statistical information about the overall success rates of procedures for external review and audit.[107] The unauthorized disclosure of confidential information, particularly donor identity, is prohibited and subject to fines in almost all of the statutes.[108]

Beyond setting standards for donor screening, the acts do not alter the usual tort law standard of care applicable to medical treatment in general. Some statutes provide that physicians are not strictly liable for the outcomes of ARTs. For example, under Louisiana law physicians are directly responsible for the safekeeping of fertilized ova.[109] However, if they act in good faith regarding screening, collection, conservation, preparation, transfer and cryopreservation, then they are not strictly liable for the outcomes.[110] Many regulatory statutes also include provisions enabling physicians to refuse patients based upon their personal beliefs.[111] These conscience clauses are commonly subject to two qualifications: the personal belief must be

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[107] E.g. *UK HFEA*, s. 13(2).

[108] E.g. *Spain*, s.9(8) makes all information other than donor identity available on demand to recipients, spouses and resultant adult children. See also *South Australia*, s. 18; *Victoria 1984*, ss.20, 23; *UK HFEA*, s.41 which prohibit disclosure of donor identity and prescribe the bureaucratic procedures to access information. This area was strictly controlled in the UK and the original rules were found to be impractical and subsequently changed, *UK, HFEA*, s.31-34. See also P. Brinsden, "News & Views: Reproductive Health Care Policies Around the World: The Effect of the Human Fertilisation and Embryology Act 1990 upon the Practice of Assisted Reproduction Techniques in the United Kingdom" (1993) 10 J. Of Ass. Rep. & Genetics 493.

[109] *Louisiana*, Ch 3.127.

[110] *Louisiana*, Ch 3.132.

[111] *Austria*, s. 6.

proven[112] and the suspension of treatment must not place the patient's life at risk.[113]

g. Control of Specific Services

Certain issues and treatments are more apt than others to be the subject of legislative intervention. In particular, the very existence of excorporal embryos and the related ability to alienate gestation triggers statutory provisions concerning: the creation and use of embryos, posthumous fertilization and surrogacy.[114]

While all acts proclaim that human reproductive materials must be respected, they diverge in the way that respect is manifested, particularly regarding the legal status and the acceptable use of embryos. For example, the Louisiana law was enacted specifically to protect human embryos. It takes the most extreme position. Embryos are deemed to be juridical persons who cannot be owned. In any disputes, adoption-like laws apply and the best interests of the embryos prevail. Courts may appoint curators to protect embryos' rights. The statute places a fiduciary responsibility upon patients and physicians.[115] If patients renounce their parental

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[112]*UK HFEA*, s. 38 provides that no one is under any duty to participate in any activity if they have a proven conscientious objection to that activity.

[113]*Victoria 1995*, s. 152.

[114]In contrast ART laws treat AI more permissively in terms of licensing and reporting. In France and South Australia, AI can be provided without a special license. In Victoria it can be provided in a doctors office or by nonpractitioners in licensed premises (*Victoria* 1984, ss. 17, 21). GIFT is also less regulated in some countries, e.g. *UK HFEA* does not apply to GIFT as fertilization occurs *in vivo*.

[115]*Louisiana*, ch. 3.124-3.127 provides that any physician who causes IVF or an ovum is directly responsible for the safekeeping of the fertilized ovum. Ch 3.131 exempts hospitals and physicians from strict liability or liability about succession and inheritance if they act in good faith and in screening, collection, conservation, preparation, transfer or cryopreservation of the human ovum. Immunity is applicable only to an action brought on behalf of the IVF ovum as a juridical person.

rights to embryo implantation, then the attending physician becomes the temporary guardian. Unwanted embryos become available for "adoptive implantation" by other married couples that are willing and able to receive them. Other statutes do not take such an extreme position. They either limit the use of embryos or provide that, through consent provisions outlined above, the sources of reproductive materials may control their subsequent use (subject to statutory limitations).[116] The statutes do not prescribe many default rules. Certain acts attempt to prevent the accumulation of stockpiles of unattached embryos by limiting the number of embryos that can be produced at one time[117] or by encouraging fertilization using gametes from at least one member of the intended recipient couple.[118] Austria takes the most restrictive position in this area. The statute prohibits both the creation of excess embryos and embryo donation. The statute specifically prohibits the use of reproductive materials for any purposes other than assisted procreation. Section 10 states that only the number of embryos that can be safely transplanted at any one time may be created. Medical treatment of embryos is allowed only in furtherance of pregnancy. Finally, all ova must be returned to their maternal sources.

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[116]*Victoria 1984*, s.14; *UK HFEA*, Sch. 3, ss. 2,5, and 6 require the consent of both gamete suppliers. *South Australia*, s. 10(3)(a) provides that the person on whose behalf embryos are stored has the right to decide how they will be dealt with and disposed of, and that the decision should be reviewed at least annually.

[117]E.g. Spain allows fertilization for human procreation only and restricts the number of embryos that may be produced to the number scientifically most appropriate for a reasonable prospect of pregnancy, ss. 3,4. However, regulated experimentation is also allowed.

[118]In France embryos may only be made *in vitro* for medical procreation. The law encourages conception using gametes of one of the recipient couple to avoid the accumulation of embryos that do not belong to anyone. However, unlike Austria embryos may be donated as a last resort if the written consent of all four parents is obtained and a judge agrees based upon the best interest of the future child, including the ability of a couple to meet the family, educational and psychological needs of the child, Art. L. 152-5.

The ability to maintain gametes and embryos outside the human body indefinitely has also triggered a promulgation of statutory storage limits to prevent perpetual storage. Ultimate limits appear in almost all ART specific enactments. The ultimate storage limits on gametes range from one year up to ten years or longer.[119] The range for embryo storage is from one year to five or ten years.[120] These periods may be cut short by the death of a gamete supplier who is also an intended recipient. Posthumous fertilisation is allowed in some jurisdictions, but prohibited in others.[121] Few acts address retrieval from corpses or embryos, but presumably this is implicitly prohibited given donor consent provisions.[122]

Embryonic therapy, research and experimentation are also controversial. If the procedures are not banned, then they are always regulated and subject to licensing.[123] Preimplantation and

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[119]*Austria*, s. 17 (one year); *Denmark*, s.15 (two years, unless the parents separate, divorce or die); *Spain*, s.11 (five years); *UK, HFEA*, s.14 (ten years);*Victoria 1995*, s.51 (any time specified by donor up to a ten year limit, unless authority allows an extension).

[120]*Austria*, s. 17 (one year this short period is explained by the fact that only enough embryos to transfer within a single cycle may be made at one time). *France*, Art. L. 152-3, *UK HFEA*, s.14 and *Spain*, s.11 (five years, in Spain they can be used after 2 years if unclaimed by source); *South Australia*, s.10(3)(c) (ten years). *Victoria 1995*, s. 52, allows storage up to 5 years as donor specifies, but discretion is allowed to delegated authority to extend this period. This provision may be a response to public reaction in UK when thousands of embryos were destroyed upon expiry of the statutory storage limit, see R. Edwards & H. Beard, "Debate: Destruction of Cyropreserved Embryos: UK Law Dictated the Destruction of 300 Cyropreserved Human Embryos Reaction" (1997) 12 Human Reproduction 3. The authors criticise the limits as a rigid law which triumphed over common sense, at 4 and comment "Some public interventions into the practice of IVF seem to be so outlandish as to make one wonder about the future direction of our field of study" at 3. See also "British Law Forces Clinics to Destroy Embryos" Globe & Mail, Aug. 2, 1996, A4.

[121]It is contemplated in UK. It is not allowed in Victoria or France. *Victoria 1995*, s. 43 bans posthumous use, s.53 provides that death requires removal from facility and so does *Denmark*, ss.3, 15 and 18.

[122]*Victoria 1995*, s.44 bans the use of zygotes, and embryos obtained from the body of a deceased woman.

[123]*Louisiana*, ch.3-122 prohibits fertilisation for research purposes. In South Australia embryonic experimentation is permitted and regulated in the *Code of Ethics*, but s. 10(2) states that the welfare of any child to be born in consequence of an artificial fertilization procedure is of paramount importance and the fundamental principle in the formulation of the code of ethical practice and s.10(3) prohibits embryo flushing, or the culturing of human embryos beyond the implantation stage. *Victoria, 1984* prohibits fertilization except for implantation in a woman,

prenatal diagnoses are often restricted to couples with established genetic abnormalities or pathologies.[124] Some statutes require that embryonic research possess therapeutic value for the embryo subject or enhance infertility technology and techniques or knowledge about embryonic development.[125] Others are more liberal, they do not restrict the numbers of embryos that can be created and used for research and development. In the UK non-therapeutic research and experimentation are allowed up to the 14th day of embryonic

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but allows licensed experimental procedures that would damage embryos and make them unfit for implantation, s.6. There are no statutory limitations. *Victoria, 1995* also permits regulated research ss.34,49 as does *France*, Art. L. 152-8.

[124]In France preimplantation diagnosis is available only if the family history indicates a strong chance of a particularly severe genetic disease that is incurable at time of diagnosis. Antenatal diagnoses is not permitted for eugenic reasons or for sex selection. To terminate the pregnancy the patient must obtain physician acknowledgment that there is a strong possibility of a particularly serious incurable disease, Art. L. 162-17.

[125]*Denmark*, s.25. *Spain*, ss.12, 13 permit intervention on live embryos in or ex *utero* for diagnostic purposes if the sole objective is the enhancement of the embryo's own viability or detection of hereditary diseases with a view to treatment if possible or (for *ex utero* embryos) with a view to advising against the transfer for procreation. Therapeutic intervention is allowed if the sole objective is to prevent spread of a disease where there are reasonable and verified prospects of success. Intervention must enhance the well being and development of the embryo or fetus. Section 13(3)defines four requirements of therapeutic procedures:

a) couple or woman must be scrupulously informed on procedures, diagnostic investigations, potentialities and risks and must accept them in advance;
b) the disease has a very precise diagnosis, a serious or very serious prognosis and the prospects for an improvement to or cure are at least reasonable;
c) a list of diseases in which therapy is possible with strictly scientific criteria must be available;
d) there is no influence on non-pathological hereditary traits and no selection of individuals or of race is sought; and,
e) the procedure is performed in authorized health centres by qualified teams with the necessary resources.

Sections 14, 15 & 16 strictly limit the use of gametes, oocytes and preembryos for research purposes. Gametes subject to experimentation cannot be used for procreation. Section 14(4) specifically allows the "hamster test" and then restricts any other forms of mixing gametes unless the National Multidisciplinary Commission allows it. Experiments are permitted subject to proper authorization if the sources provide written informed consent and receive a detailed explanation of objects of research and its implications. Research is not allowed unless it is proven the research cannot be conducted on animals and in any event research past the fourteenth day of development is precluded. There is a long list of permitted experimental purposes. Modification of nonpathological, genetic patrimony is prohibited. Experimentation on preembryos in the uterus or fallopian tubes is prohibited. Research is permitted for aborted, nonviable and dead preembryos.

development subject to certain conditions.[126] The UK act prohibits the harvesting of gametes from embryos.[127] If nontherapeutic research is allowed, the statutes restrict the subsequent use of embryos subject to experimentation. ART statutes either allow therapeutic experimentation and then dictate subsequent implantation,[128] or allow nontherapeutic experimentation and prohibit subsequent implantation absent special conditions.[129]

Surrogacy, particularly commercial surrogacy, also triggers legislative responses. It is dealt with inconsistently in the surveyed jurisdictions. Sometimes surrogacy is regulated in ART statutes and sometimes surrogacy laws are enacted separately. None of the surveyed laws adopted an affirmative policy towards surrogacy. It is either strictly controlled or directly or indirectly banned.[130] In most countries, agreements to procreate or gestate on behalf of someone else are deemed invalid or void.[131] Some statutes provide that such agreements are

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[126]*UK HFEA*, Sch. 2, s.3 permits licenses for up to three years to create, keep and use embryos for research into infertility treatment and contraception, congenital disease, miscarriage, developing preimplantation diagnosis techniques for genetic or chromosomal abnormality and any other authorized purpose that increases knowledge about the creation and development of embryos or about disease. Mixing sperm and hamster ova is allowed up to two cell stage to determine the fertility or normality of sperm. Licenses cannot authorize altering genetic structure in embryos unless specially allowed. The proposed use of human embryos must be necessary i.e. nonhuman models will not suffice. See also *Spain*, s.16 *Denmark*, s.26.

[127]*UK HFEA*, s.3.

[128]In France experimentation is only permitted in exceptional cases, the subject embryo cannot be damaged and must still be used, Art. L 152-8.

[129]*Victoria 1995*, s.40 allows implantation if special prior approval has been obtained; *Denmark*, s.27.

[130]The first surrogacy act was the *UK Surrogacy Arrangements Act* enacted in 1985 after the Warnock Report. It specifies that surrogacy arrangements are not enforceable by or against any party, s. 1A. Commercial surrogacy and related commercial activities are prohibited, ss. 2,3. The UK has relaxed its position on surrogacy somewhat. In 1995 *UK, HFEA* was amended to reverse the usual gestational link to legal maternity and allow commissioning couples to apply to the court to become the legal parents through an expedited process in uncontested cases, s. 30. *Denmark*, s.26.

[131]*Louisiana*, s.9:2713. Australian states (e.g. South Australia, *Family Relationships Act 1975*, ss. 10(g) (1), (2); *Victoria, 1984*, s.30 (3); *Victoria 1995*, s.61; and, *Tasmania, Surrogacy Contracts Act, 1993*, s.7).

not specifically enforceable. In many acts it is an offence to enable surrogacy or participate in any way such as advertising for or as a surrogate or an intermediary or providing ARTs which enable surrogacy.[132]

In the jurisdictions that permit surrogacy, the statutes utilize two means to control the procedure: special access restrictions including judicial preapproval or mandatory contract terms. In New Hampshire, the ART statute recognizes surrogacy agreements performed in accordance with rules adopted by the Department of Health and Human Services.[133] It prescribes additional prerequisites to a valid surrogacy agreement including: a medical evaluation of the surrogate; and, a home study of each party involved conducted by a licensed child-placement agency or the Department to assess the ability and disposition of the proposed parents to provide the child with food, clothing, shelter, medical care and other basic necessities. A copy of the findings must be filed with the court by each party. Further, the issuance of a birth certificate must be delayed for 72 hours during which time the surrogate may reconsider.[134] Florida law recognizes surrogacy agreements if: the surrogate was of age, the recipients were legally married, and it was determined that physical gestation was either impossible or likely to create a physical health risk to the mother or foetus.[135] The law also requires that surrogacy agreements include the following provisions: a) the surrogate

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[132]*Victoria 1995*, s. 59-61.

[133]This law deals with AI and IVF, but it was developed specifically to recognize: first, that surrogacy occurs; and second, that regulated surrogacy is preferable to unregulated surrogacy.

[134]*New Hampshire*, ss.168 B:16, B:18, B:26. See also *UK HFEA*, s.30 (1)-(7).

[135]*Florida*, s.742.15.

is the sole source of consent concerning clinical intervention and management; b) the surrogate will submit to reasonable medical evaluation and treatment and will adhere to reasonable medical instructions about her prenatal health; c) the surrogate will relinquish any parental rights and proceed with judicial proceedings about the child; d) the commissioning couple will accept custody and assume full parental rights and responsibility for the child immediately upon its birth regardless of any impairment;[136] and, e) the commissioning couple will pay only reasonable living, legal, medical, psychological and psychiatric expenses that are directly related to prenatal, intrapartial and postpartum periods. Finally, the law expedites affirmation of the legal status of the commissioning couple once they apply to the court to be recognized and provide notice of their application to the gestational surrogate, physician, and any party claiming paternity. If at least one member of the commissioning couple is the genetic parent, then the couple are presumed to be the natural parents of the child. Once the transfer of custody is complete, the birth certificate is replaced and the original is sealed.[137]

h. Child Status

Filiation and estate entitlements for children conceived through ARTs are almost always found in ART specific statutes[138] or separate family law statutes.[139] The laws are consistent regarding filiation, they affirm the participants intentions (other than for surrogacy). Donation

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[136]Unless it is determined that neither commissioning couple is the genetic parent of the child.

[137]*Florida*, s. 742.16.

[138]E.g. *UK HFEA*, ss. 27-30.

[139]*South Australia, Family Relationships Act 1975*, s.6.

generally severs parental connection.[140] Gestation and giving birth normally trigger legal maternity. Consent or declaration trigger legal paternity.[141] As in the remedial models, some regulatory statutes include additional preconditions for the application of these special rules such as the involvement of a licensed physician, marriage between the parents or spousal consent. If these preconditions are not satisfied, the status of the child is uncertain. In jurisdictions where surrogacy is allowed, additional special provisions apply to override filiation rules and transfer legal parentage to the intended parents, usually through an adoption-like procedure or a court order.[142] Most filiation laws preserve privacy on official documents such as birth certificates through sealing of original records in the case of surrogacy or the inconspicuous registration of intended parents in cases where the gestational mother will assume a parental role. In Spain, the law states that official documents should not mention ARTs. In jurisdictions that allow posthumous fertilization, ART statutes sometimes address inheritance rights. Generally these statutes put the interest in estate resolution over the child's rights. They provide that progeny will not take on usual inheritance rules, or that they may take only if they are expressly mentioned in the genetic father's will. These provisions are probably meant to prevent estate perpetuities.

i. Prohibitions

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[140]In Florida the act requires donors to relinquish all maternal and paternal rights and obligations, s. 742.14.

[141]*Spain*, ss. 7-10; *France*, Art. 311-20. Generally spousal consent precludes any challenge of filiation, absent an extreme situation such as fraud. *Louisiana* C.C., Art 188; *Florida* s. 742.11.

[142] See for example *UK HFEA*, s 30. New Hampshire gives the surrogate 72 hours from birth to assert legal maternity, if she does not then the intended couple is registered on official documents. *Florida*, s. 742.15 gives intended parents 3 days from birth to petition court to become legal parents, if a member of the couple contributed genetic materials then they are presumed to be the parents; if petition is successful then the original birth certificate is sealed.

Prohibitions are the final common component of regulatory enactments. In addition to the general prohibition against unauthorized or unlicensed activities or other violations of the respective statues,[143] most statutes identify and specifically prohibit certain unethical practices. More prohibitions are found in the restrictive statutes which directly acknowledge the public interest in protection of embryos or provide that the only acceptable use of embryos is procreation. While no specific prohibitions are universal, some are extremely common. Activities which are most likely to be condemned include:

- acting without consent of the donor or patient or in violation of consent;
- failing to adequately screen sperm or use of fresh sperm for anonymous donation;
- unauthorized disclosure of information;
- cloning;
- parthenogenesis (the development of human beings from unfertilized ova);
- combining human and animal gametes or creating chimeras;[144]
- placing nonhuman embryos into women or human embryos into animals;
- combining human gametes from multiple sources (this once was a common medical practice particularly for AI where the use of donor and spousal sperm was thought to increase the likelihood that a husband would accept his child);
- experiments on embryos past a certain stage of development such as implantation, appearance of primitive streak (nervous system) or the fourteenth day;
- replacing the nucleus of an embryo or ovum during fertilization;
- altering genetic structure of cell that forms an embryo;
- commercial transactions involving the sale of gametes or embryos;
- maintenance of reproductive materials beyond ultimate limits; and
- nonmedical sex selection.

The following activities are more controversial, they are prohibited in some jurisdictions, but permitted in others:

- surrogacy and related activities;

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[143]E.g. *UK HFEA*, s.3.

[144]Many acts include specific exceptions to account for the fact that human sperm is often combined with non-human ova to assess its viability, the resultant entity cannot develop beyond a few cells: *Spain*, s. 14(4) and *UK HFEA*, Sch. 2 , s. 3(5) which both allow mixing human sperm and hamster ova and allowing development up to two cell stage to determine the fertility or normality of the sperm.

- creating more embryos than can be safely implanted or creating embryos for purposes other than assisted procreation;
- using embryos for any purpose other than assisted procreation;
- using commercial intermediaries to facilitate ARTs;
- using egg cells obtained from embryos or fetuses;
- embryo flushing;
- posthumous fertilization; and,
- nontherapeutic or destructive embryonic research.

These prohibitions are enforced through civil liability, penalty, fine, imprisonment, professional sanction, practice restriction or licence suspension. Some acts allow a defence of reasonable excuse.[145] Others do not. Acts which include details often create inspection and investigation powers to facilitate compliance auditing.[146]

D. Conclusion

The statutes enacted at various points in time during the past 20 years illustrate the interaction of scientific advances, litigation and legislation. Highly publicised events may have been more influential in setting the political agenda and shaping reform initiatives than principled, comprehensive policy formulation. Unfortunately, these events may have unduly narrowed the statutes and ultimately led to piecemeal, reactive, ratchet-like legislation.

In an area where the RCNRT first acknowledged a range of strongly held beliefs, but then proclaimed the appropriate statutory response to be self-evident, the variety in ART statutes enacted around the world is striking. However, there are areas of general consensus or

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[145]*E.g. UK HFEA*, ss.41(10), (11).

[146]E.g. extensive inspection powers are granted in *UK HFEA*, ss.12(b), 39 and 40; *South Australia*, s.17.

commonality.[147] Foreign statutes contain four common types of laws: child status or family laws, criminal prohibitions, consumer protection laws, and laws imposing direct controls over the treatment relationship. The first type of laws govern the legal relationship amongst resultant children and their parents. The second type, criminal prohibitions, are morally based enactments designed to prevent harm to others and the destruction of fundamental societal values in ways which are practically enforceable and are not themselves harmful.[148] The main objective of consumer protection laws is to ensure patient safety and enhance patient autonomy by correcting the power imbalance and vulnerability of patients within treatment transactions. These laws typically set standards of competency and practice for ART providers; standards for the dissemination of information to recipients; and standards for donor screening. They seek to enhance, rather than limit, patient autonomy. However, in some instances patient choice is limited in the interest of patient safety. In contrast, direct treatment controls override the legal principles normally applicable to patient/physician relationships on the basis of an outside interest that may or may not involve consumer protection. These laws are not designed to rebalance information deficits or enhance patient autonomy. Like criminal laws, they are often morally based or founded upon a perceived societal interest. The laws address the reasons for seeking treatment, separating valid and invalid procedures including genetic screening and treatment for medical and nonmedical purposes. Restrictions upon the providers that are not based upon quality or safety concerns also fall within this category as do provisions concerning the financing of procedures.

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[147]See Pitrolo,*supra* note 9 at 198-206.

[148]See the Law Reform Commission of Canada's discussion of criminal law in relation to foetuses in *Crimes Against the Foetus, Working Paper 58* (Ottawa: the Commission, 1989.) Discussed in Chapter 3, above.

Treatment controls can be affirmative, such as mandatory insurance coverage. However, more frequently they are restrictive. Provisions which limit access to ARTs fall within this category including: recipient screening criteria, and limits on the creation, use and transfer of embryos. Laws which govern the use of reproductive materials outside of the human body also fall within the category of treatment restrictions. These laws address personal control over and the use of gametes; the creation, use and cryopreservation of embryos; the transfer of embryos to non-genetically related individuals; and, the wasting of embryos. Not surprisingly, certain types of laws outlined above were more likely to be found within certain policy models. Remedial models include family laws. Criminal models include prohibitions. Most regulatory models include all four types of laws.

All statutes stress the interests of children and provide for their legal status. The regulatory schemes employ administrative law components. Most acts address consumer protection (such as the screening of donated materials to secure the health of recipients and their families). They support reasoned, informed forethought and they enhance usual consent laws by proscribing the information to be disclosed and the documentation of anticipatory instructions. There is also some consensus that AI and IVF are morally acceptable, at least in the context of marriage relationships and to circumvent infertility and serious genetic disorders and diseases. The acts do not address the key issue of who will pay for the procedures. The acts do not apply to other procedures which restore reproductive function, but do not sever genetic patrimony. AI tends to be less regulated in recognition of the fact that it involves less technical expertise. The existence of *ex utero* embryos triggers more rigorous legislative controls regarding experimentation and surrogacy. But ultimately, while

there is a general consensus about the importance of human dignity, there is much less common ground about how this concept translates into legislative control over ARTs.

> [A]s Dame Warnock recognized over ten years ago, the precise point of the dispute is not on the value that should be attached to human life in general, but rather the value that should be attached to human life at its very earliest stage of development.[149]

The main points of differentiation evident in the legislation are morally based, they concern the acceptable uses of human embryos, acceptable recipients of ARTs, the need for a genetic maternal nexus and the need for donor anonymity. The root of many of these differences lies in the relative emphasis placed upon self determination and procreative autonomy and the principle of human dignity and personhood encompassed in reproductive materials. [150]

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[149]*Ibid.* at 198 citing The *Warnock Report* at xv in Mary Warnock, *A Question of Life, the Warnock Report on Human Fertilisation and Embryology*,(Oxford: Basil Blackwell Ltd., 1985).

[150]For example, self determination and procreative autonomy are key in the UK and Spain, but not even mentioned in Germany: Bernat & Vranes, *supra* note 7 these differences between the UK and Austria and Germany as follows at 331:

> The extremely liberal English approach, on the other hand, can be traced back to the underlying ethical concept, which stresses procreative autonomy and does not grant the embryo the right of human dignity.
>
> In other words, these vast legislative differences in the laws of Austria, German and England - all signatories of the European Convention on Human Rights - can be seen as results of, grossly speaking, divergent basic ideological questions: "What should be allowed?" in Austria and Germany, *vis-vis* "What should be prohibited?" in England.

CHAPTER SIX: *A Statutory Overlay for ARTs in Canada*

Procreative assistance has traditionally been considered a medical matter dealt with by individual patients in private consultation with their physicians. It has been analysed from that perspective throughout this work. With the advent of ARTs and IVF in particular, public interest and regulation in this personal area has increased around the world. While other pressing issues including other life-saving medical activities have not been the subject of detailed political scrutiny, many governments have added unprecedented legislative controls to this aspect of medical practice. In Canada, the federal government appears poised to join this trend and to traverse the international legislative span by abandoning the current *laissez faire*, physician-dominated approach in favour of a criminal model with severe sanctions rivalling those enacted in Germany and Austria. This chapter assesses the merits of this proposed policy change and of any ART specific statutory overlay to control, complement or replace the existing legal mechanisms and safeguards applicable to patient/physician relationships. Drawing from earlier chapters, ARTs are put into their legal context. The unique characteristics of ARTs, the need for additional legal controls and the possible form of such controls are considered with reference to three models found in Canadian law reform proposals and foreign statutes.

A. Canadian ART Regulation: A Review of The Existing Legal Landscape

By virtue of physician involvement, ARTs occur within the medical treatment context and are subject to several common law rules. Physicians must exercise the care and skill of the average prudent physician in diagnosing, treating and referring patients. Physicians are legal fiduciaries expected to put their patients' interests first and to respect the ethical principles

of autonomy, justice, benefice, and nonmalefeasance. The informed consent process ensures patient autonomy. Prior to providing treatment, physicians must disclose all information that a reasonable patient would want to know regarding his/her condition, the nature of the proposed treatment and associated success rates and risks, and the relative risks and benefits of alternative treatments. Physicians must maintain information derived from patient/physician relationships in confidence, but the information is not legally privileged.

In addition to the common law rules, the Canadian constitution has shaped Canadian laws which apply to ART transactions. The *Charter* does not create a positive right to fully-funded ARTs on demand. To date the judiciary has been reluctant to interfere in resource allocation decisions, particularly macro-level decisions about the provision of specific services or medication within the provincial health care insurance systems. However, if a government elects to regulate or to provide ARTs, then the *Charter* and provincial human rights laws limit the degree to which personal rights inherent in patient/physician relationships may be restricted, particularly the degree to which access may be restricted based on the personal, immutable characteristics of potential users such as marital status, age and sexual orientation.

The Constitution implicitly divides legislative authority over health care. Both the federal and provincial governments have enacted legislation concerning medical services. Parliament derives its authority from several limited sources, mainly the authority over spending, criminal matters and matters of national concern which the provinces cannot properly control. The federal government has been very involved in health matters, exercising considerable steering influence through its funding powers. It has also regulated medical devices and drugs in the

interests of safety. While national ART standards are commendable, these federal sources of power do not support the enactment of a comprehensive regulatory system to govern human reproduction, genetics and the provision of ARTs in Canada. Such an enactment would represent a significant intrusion into provincial authority and an unwarranted alteration to the constitutional balance of legislative authority.

The provinces have assumed a dominant role in health care, particularly with respect to the delivery of services and regulation of the professions based on their authority over property and civil rights and matters of a purely local or private nature. All provincial governments have established health insurance schemes to cover the costs of medically necessary services through a tariff of fees negotiated with the medical profession. Not all medical services are funded. Uninsured services, including IVF and ICSI, are available within a residual private market. The provinces regulate hospital services, physician services and the delivery of medical services through licensing and a self-governance model within which the medical profession enjoys a high level of professional freedom. Provincial statutes do not generally dictate details about the provision of specific services. Patient autonomy and professional judgment prevails, subject to the common law principles listed above. In addition to health care related laws, a few provincial enactments deal with legal paternity of children born through ARTs. Quebec alone has enacted a law invalidating all surrogacy contracts and authorizing the release of medical information to children conceived through ARTs. Recently guidelines for experiments involving human subjects including human gametes, embryos and fetuses were produced by three federal funding agencies and new ART policy statements were issued through the cooperative efforts of two national professional bodies. In 1996, an earlier

version of the practice guidelines had been incorporated by reference into federal regulations enacted which established national standards for the storage and use of semen in connection with ARTs to minimize the transmission of infectious diseases.

While Canadian ARTs related jurisprudence is limited, some discernable principles have emerged. First, once born, the progenies of ARTs are treated like any other children. Courts determine child custody and status based upon the child's best interests regardless of the means of conception or the terms of contractual arrangements amongst interested adults. In accordance with the best interests principle and the *Charter*, nontraditional families are increasingly receiving judicial recognition and access to rights previously reserved for traditional families. Second, courts recognize the unique value of procreative capacity. They view ARTs as an acceptable means to overcome physical barriers to reproduction. Third, physicians providing ARTs are expected to comply with the common law principles applicable to all other forms of medical treatment. Fourth, courts are reluctant to order provinces to provide free ARTs on demand. However, if ARTs are provided within the basic insured bundle of services, they must be provided in accordance with the *Charter* and provincial human rights laws. Also, it is very difficult for patients to assert autonomous rights where they conflict with those of medical providers. There are no formal patient appeal systems and the judiciary generally adopts a very deferential stance toward medical professionals.

While it is hard to draw conclusions from such a small sample, to date the cases seem to demonstrate that in the absence of formal regulation, professional standards may provide insufficient assurance for the safety or constitutional rights of potential recipients. This is

supported by the findings of Canadian law reform commissions which have studied ARTs. Some commissions accepted the current self-regulating model. Others raised concerns about its efficacy, particularly its failure to ensure the creation or implementation of consistent practice standards. A patchwork collection of unexplainable discrepancies and unproven, unsafe and unethical medical practices were revealed by the extensive research efforts of the RCNRT and repeatedly cited them to justify sweeping federal legislation.

B. What's All the Fuss Really About? Law, Science and the Nature of ARTs

Science, like urban development, often sprawls forth at an unwieldy and unpredictable gait which can create alarm and outdate existing laws and efforts at legal reform. Recent examples include the Internet, bioengineered food products and computer chip technology. Accelerated rates of development create severe tension over the efficacy of existing social and legal controls and the need for novel laws to govern all aspects of technology from common transactions and conflicts to more unusual situations.[1] While ARTs represent only one manifestation of this common debate, they also possess unique characteristics which complicate the search for an appropriate legal response and generally militate in favour of some external control.[2] At the core of many of these unique characteristics is disagreement concerning the value and respect that should be accorded to human life at its earliest stages.

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[1]Typically debate centres first on the need for limits and then on an appropriate control mechanism: R. Swidler, "Medical Innovations and Ethics: A State Government Perspective" (1994) 57 Albany L. R. 655 at 657-659.

[2]Traditionally legislators have been reluctant to regulate medicine because of the nature of the patient/physician relationship; the intrusion upon scientific and contractual freedom; and the private nature of family and pregnancy: L Nielsen, "From Bioethics to Biolaw" in C. Mazzoni, ed., *A Legal Framework for Bioethics* (The Hague: Kluwer Law Int., 1998) 39. See also M. Somerville "Are We Just 'Gene Machines' or Also 'Secular Sacred'? From New Science to a New Societal Paradigm" (1996) 17:2 Policy Options 3 where the author discusses these unique factors and the need for a legal framework to balance science against spirit.

Unlike many other novel technologies, ARTs are subsumed within the politically volatile arena of human reproduction and reproductive rights. In this arena there are a vast array of fiercely held beliefs concerning morality, power relationships and the roles of medicine and law. The views are extremely polarized, suggesting that science itself, rather than political compromise, will ultimately resolve the key differences.[3] Law and reproduction have had a tumultuous past which often exposed the biases and hypocrisy of social norms and the clash between these norms and individual autonomy and privacy. In the past, criminal prohibitions have been used to control human reproduction, often with disparate and negative effects for women.[4] More recently, reproduction has been subject to less legal interference. The federal government has decriminalized contraception and left abortion unregulated for more than ten years. Morally inspired provincial abortion laws have been overturned. Sterilization laws have been repealed. Individuals have more control over procreation. Potential parents are free to obtain *in utero* fetal testing and to act in accordance with their consciences regarding continuing with pregnancy. Human embryos and fetuses are not recognized juridical persons and therefore are not entitled to constitutional rights and protections. Accordingly, judicial interference in pregnancy is restricted as the interests of the mother prevail in law.

ARTs raise the externalities normally involved in the provision of all medical treatment. They

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[3]In the area of reproductive rights "[i]t has been difficult to establish a consistent national policy, especially in such controversial areas as reproductive and family matters, where the strategies of bargaining and compromise that are central to legislative policy making often prove ineffective" R. Blank & J. Merrick, *Human Reproduction Emerging Technologies, and Conflicting Rights* (Washington, D.C.: Congressional Quarterly Inc, 1995) at 22.

[4]S. Martin, "An Overview of the Legal System in Canada" *Overview of Legal Issues in New Reproductive Technologies: Research Studies of the Royal Commission New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply & Services Canada, 1993) 85 at 117-119.

also raise unique externalities.[5] Their very existence may be threatening because they sever the traditional nexus between marriage, sexual relationships and reproduction as well as the coincidence of genetic and social parentage. Unlike other forms of procreative assistance, ARTs involve the deliberate physical separation of reproductive materials and embryos from their human sources, enabling possibilities beyond genetic gestation or destruction. This challenges established social norms and raises fear that science is pursuing unacceptable goals. Public concerns are heightened by the combination of ARTs with genetic advances which reduce some of the previously inherent randomness of reproduction by allowing sex and trait selection through preimplantation screening, selective reduction and cloning. This unprecedented severance and ability to control characteristics of the potential child make procreation and a child of one's own more of a commodity than in the past. They also raise concerns regarding genetic discrimination and eugenics in general.

Severance also means that the number of interested parties and participants is larger than with other medical treatments or procreative decisions. As ARTs are continually refined to increase the chances of producing a healthy child, the number of involved parties and interests expands as does the likelihood for conflict.[6] Sexual procreation and traditional procreative assistance involve only two parents. Extensive divorce and adoption laws govern breakdown and contingencies. With ARTs, up to eight parents have been involved in the creation of a single

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[5]See generally M. McTeer, "A Role for Law in Matters of Morality" (1995) 40 McGill L. J. 893.

[6]Advances which solve certain infertility problems often create unexpected side effects including the potential for future disputes and the need for just legal resolution. For example, cryopreservation has made it possible to create a virtually unlimited number of embryos and to preserve them indefinitely. It also enabled situations involving disputes over care, control, custody or ownership of embryos because individuals have a greater opportunity to "parent" in the sense of exercising care and control over embryos.

child and very few laws govern breakdown or contingencies. Many ARTs involve donated genetic material. Donors are not parties to patient/physician relationships, but their interests are affected by the use of their gametes and the maintenance of confidentiality about their involvement. Finally, with ARTs such as ICSI and surrogacy, the patient subject to the treatment is not necessarily the party suffering a fertility or genetic impairment and may not even be the party to receive the ultimate benefit: a child of one's own.

Finally, unlike other technologies, the media has played a major role in shaping public opinion. Reporting about the emotional aspects of ARTs has shaped public perceptions and further polarized diverse views. The significance of publicised events is reflected in the law reform materials and foreign legislation.[7] Sensationalised reporting of ART discoveries and legal disputes has increased scrutiny of technological progress and existing laws. Public unease increases existing pressure to respond to and affirm human dignity by controlling individual actions of patients and physicians through law. This uneasiness has been exacerbated by the piecemeal, inconsistent and often unsatisfactory judicial resolution of difficult disputes.

These unique characteristics and forces, while compelling, do not necessarily justify the passage of novel legislation.[8] Together these characteristics and forces, particularly the perception that controls are required, have placed pressure upon legislators to produce

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[7]Such as AIDs, custody disputes, posthumous donation and estate litigation, see Chapter 5 above. See also P. Hopkins, "Bad Copies - How Popular Media Represent Cloning as an Ethical Problem" (1998) 28:2 Hastings Centre Report 6 for a discussion of media and public perceptions of cloning and the need for legal controls.

[8]Indeed, some forces , such as the lack of moral consensus, militate against the promulgation of specific statutes, see generally Blank & Merrick,, *supra* note 3 at 17-22 and A. Bonnicksen, *In Vitro Fertilization Building Policy from Laboratories to Legislatures* (New York: Columbia University Press, 1989).

tangible legal responses. They can provide more insight than the explicit statutory provisions or accompanying materials about why medical professionals, trusted with a monopoly over a myriad of life and death services affecting vulnerable individuals, have become subject to unprecedented external controls.

C. A Legal Framework for Canada

Against this backdrop it is easy to be diverted by current events. There is undeniable pressure on legislators to do something. However, the "right thing" remains controversial. While an optimal legislative solution is not obvious, certain principles guide the policy formulation process and narrow the options:

- First, several values must be weighed: individual interests in privacy, freedom, autonomy, equality, equity and dignity; and, societal interests in human dignity, prevention of discrimination or commercialization of reproduction, and scientific and individual freedoms.[9]
- Second, the law must adhere to the Canadian Constitution.
- Third, following the *Charter*, as well as the general principles of legislative restraint and the private and personal nature of reproduction and medical treatment, legal policy must respect individual rights including autonomy within patient/physician relationships. Individual choice should be subordinated only if an outside interest is threatened or frustrated without regulation. As far as possible, issues should be left to be determined by patients and physicians free from regulatory interference.
- Fourth, ART policy must be reconcilable with other health and reproductive policies.
- Fifth, the costs and benefits of legal alternatives must be considered, particularly if ARTs are financed out of the limited pool of public resources. The benefits of changes to existing bodies should be measured against those of entirely new administrative structures. An overlay of bureaucratic involvement and licensing should be adopted only

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[9]See Nielsen, *supra* note 2 at 40-41.

if current systems prove inadequate.[10]

- Sixth, consideration must be given to the purpose of the law[11] and likelihood that the law will achieve its desired objective. The simple enactment of a law cannot guarantee compliance. If a law is too restrictive, it may be disregarded entirely. The optimal law must account for the likelihood of compliance and address noncompliance.

- Seventh, while the experiences of other jurisdictions may be helpful, they are not always transferable due to contextual differences. A Canadian solution does not have to accord with the policies of other nations. A restrictive policy may be justified regardless of the spectres of procreative tourism or illicit activity. The legal entrenchment of the lowest common international denominator of regulation may inappropriately import a poor and inadequate policy.

Reasoned policy formulation involves defining all current and potential practices, considering whether they are acceptable and then determining the most appropriate legal means to ensure that the activities do not occur, occur freely, or occur in limited circumstances only. More particularly, this is achieved through a two-step process: systematic identification of issues which require legislative intervention and selection of an appropriate control mechanism to govern those issues. The key ART transaction elements must be sorted into three categories: those that can be decided by individuals within patient/physician and other relationships; those that can be governed through professional self-governance and professional standards; and, those for which societal interests must be expressed through law to guide or limit individual

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[10]In the words of the Canadian Medical Association, *Human Reproductive an Genetic Technologies Act, Brief Presented to the Sub-Committee on Bill C-47* (Ottawa, 1997) at 2:

> These technologies are just one set of medical procedures that can be used for good or ill. In Canada we have developed a sophisticated set of mechanisms to regulate such procedures, the training required to perform them, and the facilities where they take place. If it can be shown that this regulatory framework is not dealing adequately with the reproductive technologies, we suggest that instead of creating an entirely new, untried and expensive structure the existing one should be made to work better.

[11]Law can be used to define societal norms of acceptable behaviour, to protect vulnerable individuals or to provide certainty for participants. Foreign ART statutes contained four common types of laws: filiation and estate laws; criminal prohibitions; consumer protection laws; and, direct treatment transaction controls.

choices. Consistent with the principles set out above, particularly respect for individual autonomy and regulatory restraint, statutes should address only issues in the latter two categories.

Step 1: Identifying Specific Issues Warranting Regulation

The following aspects of ARTs fit into the two latter categories and may require legislative intervention: patient safety; use of genetic materials, patient access; physical separation of gametes, embryos and their intended recipients, separation of gestation and parenting, experimental use of embryos; genetic testing and manipulation; records and filiation.

Patient Health and Safety: ARTs are invasive procedures that carry health risks; therefore, participants deserve assurance about the quality and safety of ARTs.[12] There has been great concern over the speedy introduction of ARTs into the therapeutic realm and concern regarding the purposes or situations in which they are used. The *terNeuzen* case and the deficiencies chronicled by the RCNRT and other commissions suggest that ART specific intervention in the name of safety, quality and public health may be appropriate. Consumer protection laws are justified by the public interest in ensuring patient safety. While these issues are covered by the common law, they have also traditionally been affirmed and enhanced in legislation. These laws generally strengthen patient autonomy by correcting the knowledge imbalance and vulnerability of patients involved in treatment transactions.

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[12]J. Martin, "Prioritising Assisted Conception Services: A Public Health Perspective" D. Evans, ed., *Creating the Child* (The Hague: Kluwer Law Int., 1996) 241 at 246.

Use of Donated Genetic Material: Donor involvement may justify legal intervention over and above traditional safety and screening concerns raised by invasive procedures. Donors are not patients (they may not even be persons). Their relationships to physicians are contractual and their relationships to recipients are tortious. The fiduciary obligations of patient/physician relationships do not apply to donors. Therefore, legislation may be required to ensure minimum conditions concerning disclosure and confidentiality. Given that the donor's interests are affected by the use of their reproductive materials and given that the privacy and confidentiality interests of the donor may conflict with the child's right to full knowledge of his or her biological origins, legislation is required to control the flow of information amongst participants.

Patient Access and Choice of Treatment: Canadian reform studies and jurisprudence reveal discriminatory barriers and unwarranted variations in individual access policies. Under the common law, anyone may seek medical treatment and may then weigh the alternatives and choose their course of treatment in consultation with physicians. While many ART statutes restrict access on medical and social grounds, legislation may be needed to assure fair access and compliance with the *Charter*.

Physical Separation of Gametes, Embryos and Intended Recipients: The deliberate separation of physical custody of reproductive materials and embryos from their human sources creates the potential for disputes over their care, control, custody and ultimate use. These disputes can arise between potential recipients or amongst recipients and providers. The parties and the interests of the embryos suggest that regulation to ensure predictability

and just resolution is warranted through set rules or enhanced consent procedures.

Separation of Gestation and Parenting (Surrogacy): Surrogacy is practised commercially and noncommercially in Canada despite a voluntary moratorium and pending federal prohibitions. Regulation of this ART may be warranted for several reasons. The surrogate patient bears the risks of treatment, but does not receive the benefit of a child of her own. The surrogacy relationship is not a part of the physician/patient relationship and the two relationships may conflict. The surrogate may be in a vulnerable position relative to the commissioning couple or to another intermediary. Unlike other donations, surrogacy is an intimate, lengthy process during which the surrogate's interests become entwined with those of the child. The separation of gestation and parenthood culminates in the transfer of custody of a legally recognized person, rather than gametes or embryos with the potential to become persons. Surrogacy agreements may run afoul of the common law prohibition on sale of children. Finally, as traditional law determines parenthood based upon gestation and then genetics, it does not automatically affirm the intended family unit.

Experimental Use of Embryos: ARTs enable the creation of vast numbers of embryos. The profession and the law have recognized a need for regulation of the use of all human experimental subjects, especially for those who cannot provide informed consent. While the embryo is not considered a legal person, it is an entity deserving of respect so some external limits are warranted.

Genetic Testing and Manipulation: ART recipients have been able to choose donor

characteristics for many years. Genetic advances enhance choice and the ability to reduce some of the randomness previously inherent in reproduction. The ability to detect, control and eliminate genetic characteristics of human embryos tends to commodify procreation and the concept of a child of one's own. While extreme cases may be obvious, it is very difficult to determine what constitutes a genetic impairment or disease in need of correction or elimination through ARTs. These techniques raise broader concerns regarding the value of all types of human life and human dignity in relation to genetic discrimination and eugenics in general and therefore external limits are warranted.

Long Term Maintenance of Records and Identifying Information: Many of the legislative interventions suggested above presuppose a system for the collection and maintenance of extensive documentation about ART users and long term outcomes for the children. This necessarily involves the use of private information outside patient/physician relationships and donor/physician relationships. The maintenance and use of long term studies and linked records raises issues of confidentiality. The risk of misuse or disclosure and the interests of children and donors suggest that regulation should be considered.

Filiation: Filiation is the most commonly legislated topic and all reform commissions recommended that it be dealt with by statute. Under existing laws, the separation of gestational, genetic and social parentage misaligns legal and factual families. This misalignment justifies legislative attention.

Step 2: Weighing Legal Alternatives

Once the issues warranting regulation have been identified, alternate means of legal control can be evaluated. There are three policy options based upon the Canadian reform proposals and the foreign statutes: penal, *laissez faire* and regulatory.

OPTION A: The Penal Model

Proponents of this model "invoke moral and sometimes religious objections, and contend that the [ART] innovations will invariably lead to grotesque abuses."[13] Accordingly, criminal prohibitions such as Bill C-47 are enacted to prevent anticipated abuses before they materialize. Once an activity is well established a simple criminal prohibition may no longer be feasible. Criminal prohibitions outlaw specified activities on the basis of morality or utility to prevent demonstrable harms which clearly endanger society.[14] As they are the most draconian and rigid legal instruments of social control, criminal laws are used sparingly when other legal controls cannot adequately protect public interests and only when they are practically enforceable and do not themselves become harmful or bring law into disrepute.[15]

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[13]R. Swidler, *supra* note 1 at 657-658. See e.g. S. Scorsone, "Prohibit Commerce in Human Reproduction", March 1996 *Policy Options* 18 who uses summarized anecdotes and self-evident truths to conclude that "for most people the very idea of commercializing human reproductive is repellant."

[14]See P. Healy, "Statutory Prohibitions and the Regulation of New Reproductive Technologies Under Federal Law in Canada" (1995) 40 McGill L.J. 905.

[15]This point is emphasised with reference to ARTs by M. Hudson, Senior Counsel, Health Canada Legal Services Unit Department of Justice (Canada) in "Societal Controls on New Reproductive Technologies: A Canadian Perspective" in *Governing Medically Assisted Human Reproduction: Report of An International Symposium* (1997) 73 at 79:

> The federal government has long maintained that restraint should be used in employing the criminal law. We cannot lose sight that the basic nature of criminal sanctions is punitive and coercive, and, since freedom and humanity are valued so highly in our society, noncoercive, less formal and more positive approaches are preferred wherever possible and appropriate. We must also keep in mind, that if the criminal law is used indiscriminately to deal with a vast range of social problems of widely varying seriousness in the eyes of the public, then the authority, credibility and legitimacy of the criminal law is eroded and depreciated.

Criminal prohibitions clearly fall within the federal legislative power and they may be quite detailed if the underlying purpose is criminal in nature.[16] There is strong symbolic value in labelling abhorrent behaviours criminal. Criminal law may address some extreme aspects of ARTs on a societal level, by expressing community values through stigmatizing dangerous activities. However, it is not optimal as an exclusive policy for many reasons.[17] Bill C-47[18] represents a typical criminal policy which amply illustrates the shortcomings of this model.

The first great obstacle to criminal policy is the lack of consensus on the morality of ARTs. Opposing perspectives are founded on ethical principles and moral grounds. Disagreement is acute regarding a key issue at the heart of policy creation - the proper means of legal recognition of the dignity and value of the potential for human life embodied in human reproductive materials and human embryos.[19] Criminalizing behaviour in the face of such

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> The lumping together of seriously harmful and wrongful conduct with a host of technical, minor or controversial matters blunts the impact and undermines the effect the criminal law should have as society's institution of ultimate recourse.

[16]See Chapter 3 for cases which demonstrate the breadth of federal criminal law authority.

[17]For general criticism of the use of criminal law see Martin *supra* note 4 at 117-120; Canadian Bar Association, *Submission on Bill C-47 Human Reproductive and Genetic Technologies Act* (The Association, 1996).

[18] *Human Reproduction and Genetic Technologies Act*, 2nd sess., 35th Parl., 1996 The Bill was to be part of a larger regulatory policy discussed in detail in Chapter 3 above. The government never clearly justified the use of criminal law. In *Setting Boundaries*, the federal government argued that criminal law was warranted because the prohibited ARTs either offend the principles of respect for human life and dignity, failed to protect the vulnerable (the unborn and women) or were simply unethical. According to the government, the current system which allows commercial involvement will inevitably lead to immoral commercialization.

[19]In *Crimes Against the Foetus, Working Paper 58* Law Reform Commission of Canada (Ottawa: the Commission, 1989) at 12, the LRCC aptly makes a case restraint:

> Such irreconcilable moral differences reveal the limits of law as a coercive instrument. By choosing one defensible moral position over another the state rejects the dissenting moral stance together with its religious underpinnings, if any. Societies like ours, which cherish freedom of conscience and individual autonomy, must obviously reject state imposition of one particular moral view, on others conscientiously holding opposing views equally defensible.
>
> Here, then, as elsewhere, criminal law must be used with restraint. It shouldn't be used to prevent

disagreement may be politically impossible, and, as with other reproductive issues, it may create additional conflict which ultimately brings the law itself into disrepute.

Even if a social consensus regarding the morality of ARTs emerged, criminal law is blunt, rigid, excessively punitive and probably ineffective as an exclusive means to control ARTs. Criminal prohibitions can only address certain ethical issues, they are ill equipped to balance multiple interests and circumstances raised by ARTs. Criminal prohibitions are intended to identify, punish and deter unacceptable procedures, not to control the provision of lawful medical treatments. They cannot address more traditional regulatory objectives such as quality assurance through credentialing, licensing and monitoring or the protection of patient rights within patient/physician relationships.

Penal statutes are formulated through the democratic political process. While medical professionals may have some input into this process, their participation is not guaranteed. The translation of fundamental values and protective measures into harsh, static statutory prohibitions may not effectively reflect medical and clinical realities. Given the rapidly developing nature of ARTs and the imprecision of legal language, prohibitions can be outdated or overly broad leading to a chilling effect upon licit activities and future research

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abortions in circumstances where it is widely regarded as morally defensible. This doesn't mean however, that it can't be used to protect the foetus where there is no justification for its destruction, that abortion is the only or best response to the dilemma of woman pregnant against their will, or that the state should not in its role of furthering the common good protect the unborn through non-coercive means....

The LRCC's recommendations also received disagreement see Martin, *supra* note 4 at 117.

and development.[20] Frank communication, essential to patient/physician relationships, may be unduly restricted by the desire to do the legal thing, rather than the moral thing.

As procreation is profoundly personal, enforcement could prove impractical or possible only through serious violations of personal privacy and constitutionally guaranteed rights. It will be difficult to prove individual criminal liability beyond a reasonable doubt, particularly as ARTs involve the cooperative efforts of many individuals. Further, criminal statutes apply universally. While sentencing may vary, there may be little prosecutorial discretion to address the factual differences between cases.[21] The stigmatizing effect of criminalization can be deleterious for ART, a technology already shrouded in secrecy and shame. It is difficult to see how punishing parents through criminal convictions, severe fines or incarceration could further the Bill's professed purpose, to protect embryos, children of ARTs and women.[22] Rather than protecting the progeny of ARTs, criminal laws make them pay for the transgressions of their parents.

In sum, a purely criminal law model of ART regulation is overly restrictive and inconsistent with the principle of the regulatory restraint and current policies regarding health care and reproduction. Controversial criminal statutes are difficult to pass and to revise through the

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[20]Bill C-47 is overly inclusive in several ways: it was enacted to protect against known and unknown threats to human dignity, health and safety, the prohibitions are defined descriptively but are somewhat vague and overly broad. As drafted, it may well prohibit two common practices: reimbursement of donor expenses and a male fertility testing technique employing hamster ova.

[21]Bill C-47 applies indiscriminately to providers, facilitators and patients. If enforcement is through the criminal code, rather than a separate federal enactment, then prosecutorial policies could vary from province to province.

[22]If custody litigation is considered harmful for the children of ARTs, what are the deleterious effects of convicting parents and physicians for the crime of creating those same children?

public, political process. Penal laws such as Bill C-47 are rigid, blunt and excessively punitive legal instruments which restrict lawful scientific and personal freedoms and licit activities. Furthermore, penal laws set out the conditions under which ARTs may not proceed, however, they cannot address a more crucial concern, the conditions under which ARTs may proceed. Other legal instruments can be equally coercive, yet more comprehensive, relevant and responsive.

> The criminal law has never been entirely suitable as a medium for the expression and enforcement of public morality. Similarly, the law has never been tractable as a means for regulating the expansion of science. The double challenge posed by NRGTs is to harness the law so as to mediate between moral imperative and the therapeutic or non therapeutic benefits of the advancement of science.[23]

OPTION B: The *Laissez Faire* Physician-Dominated Model

Until recently, *laissez faire* best described Canadian ARTs policy. Leaving ARTs unregulated is a policy decision to support individual choice expressed through freely made agreements and to leave disputes to be resolved through adversarial litigation. A pure *laissez faire* model is not possible because absent specific legislation, generally applicable laws and professional codes apply. A *laissez-faire* model by definition avoids unnecessary bureaucracy and needless restrictions on individual and scientific freedom. This model complies with the *Charter* and the constitutional division of legislative authority. However, it has three general drawbacks: dominance of individual interests (particularly those of physicians) to the exclusion of other interests; uncertainty for participants; and, a tendency to use family law inappropriately.

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[23]P. Healy, "The Criminalization of New Reproductive and Genetic Technologies" in L. Weir, ed. *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) 65 at 70. See also B. Dickens, "Do Not Criminalize New Reproductive Technologies" (1996) March Policy Options 11; and Healy, *supra* note 14 at 927- 930 describing a continuum of coercive measures.

In the treatment context, the *laissez faire* model contextualizes or individualizes ethics, leaving key decisions to patients, individual providers and the medical profession. It fails to adequately balance collective effects and individual decisions and desires or to account for the interests of disadvantaged parties.[24] Unfortunately, common law principles such as autonomy may be inadequate to deal with all aspects of ARTs. The immediate concerns of patients and providers may eclipse all other issues. The desire for a child of one's own may overwhelm any broader or longer term societal interests. This conflict is not addressed by the common law rules applicable to patient/physician relationships.

The *laissez faire* approach also bolsters the physicians' position of power and fails to recognize the inherent conflict physicians experience within the professional agency health care system adopted in Canada. Absent ART specific statutes, ARTs will be developed and provided largely in accordance with the wishes of the medical profession and the institutions that offer these services through medical intermediaries. Professional guidelines or standards may provide detailed direction and assistance in retrospective litigation. They can be more effective than other types of laws if compliance is mandatory and membership in such organizations is a prerequisite to professional practice and if expulsion amounts to professional capital punishment.[25] However, the content and binding effect of these codes is

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[24]See generally H. Leenen, "Health Law and Health Legislation: Possibilities and Limits" (1998) 49 I.D.H.L 77 at 80. He provides the following preconditions for a true self regulating system: full participation by all parties; equality in terms of power; prevalence of common over individual interests; binding effect on rank and file; regulation must be open and controllable; appropriate enforcement measures. He concludes that codes set by providers are inadequate to govern patients' rights.

[25]Canadian guidelines have been promulgated by various professional groups; however, their effectiveness is unknown. The Supreme Court of Canada found the industry standards inadequate in the mid 1980s and the RCNRT found the self-regulation model inadequate in the early 1990s. The 1999 CFAS and SOGA policy statements and national research councils guidelines for human experimentation may be more effective. However,

frequently up to the complete discretion of the very professionals interested in providing the services in issue. Guidelines prepared by professional bodies may inadequately reflect the interests of recipients and other groups. They are often less onerous than independent statutory or regulatory controls and may not provide adequate protection for patients, particularly in the private market setting where public funding is not a threshold determinant of activity. Although guidelines can be written in a proscriptive manner, they do not have the force of law unless properly authorized in a constituent statute.[26] Without external regulation, there is no obligation to create, evaluate or audit practices in order to ensure that evidence-based medicine is practised.[27] Finally, regardless of the legal enforceability of guidelines, compliance may be poorly monitored or enforced.

The second main drawback of a *laissez-faire* system is uncertainty. It is particularly acute given the dearth of Canadian case law about ARTs and the respective rights of participants. This uncertainty creates problems for all participants. While legislation can never guarantee acquiescence, it can provide welcome guidelines for those providers willing to comply and

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these professional associations and organizations are federally incorporated organizations, their constitutional authority to formally regulate the provision of medical services and the medical profession is suspect. The councils were constituted to promote and in some cases perform, research; to disseminate information and to advise the federal Minister on recent developments. These funding and research councils were not constituted to provide mandatory codes of conduct for the provision of therapeutic medical services. Furthermore, each policy statement provides that it "reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institution can dictate amendments to these opinions. They should be well documented if modified at the local level."

[26]Professional guidelines may have the force of law through provincial and federal enactments which incorporate the self regulating professional groups and specialized associations. Self regulation with force of law is dealt with below in the regulatory model.

[27]See also P. Neumann, "Should Health Insurance Cover IVF? Issues and Options" (1997) 22 J. of Health. Politics, Policy & L. 1214 at 1223. C. Mazzoni, ed., "Bioethics Needs Regulation" *A Legal Framework for Bioethics* 3 at 4-5 where the Italian situation is used to show the deleterious effects of a total absence of regulation.

it can avoid disputes. Legal limits benefit professionals who experience discomfort with certain practices and the uncontrolled technological imperative. Absent legislation, the judiciary takes on the role of legislator and the law develops incrementally in the common law tradition. This is unsatisfactory for several reasons. Judicial pronouncements are reactive. Individual rulings regarding medical treatment and child custody are often fact specific and possess little or no precedential value. They arise out of adversarial situations which emphasize the particular rights and conflicts at issue, rather than the creation of cohesive and comprehensive policy. Fragmented policy development through individual assertions of rights in isolated cases can create confusion and conflict leaving the subsequent participants in even greater uncertainty. Furthermore, the litigation process creates limited opportunity to consider external policy factors and objectives. Nonparties may only be heard through third party standing or intervenor status. Even if they are heard, their involvement is limited by the facts of the case at issue. Legal redress is predicated upon compensable damages, disputes may not involve legally recognized or compensable wrongs. Finally, litigation fails to account for the relative power positions of potential patients and physicians. Few patients can assert their rights or question medical decisions through this public, cumbersome, timely and expensive process.[28]

The third drawback of the *laissez faire* approach is the propensity to use family law for

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[28]Canadian cases show how difficult it can be for individual patients to assert their autonomy or to insist that doctors adhere to common law rules of patient/physician relationships, see chapter 3 above.

regulatory purposes. These models typically include laws to establish filiation.[29] Since the statutes presuppose the existence of living children, they in theory do not have direct effects upon patient/physician relationships or the provision of ARTs *per se*. However, certain conditions may be required to trigger the ART specific family law regime.[30] Within this contract compliance system patients must either satisfy certain conditions in return for legal recognition of their intentions or they must assume the additional risk that donors and surrogates may assert parental rights. Offspring and parental rights often arise only if ARTs are provided by licensed physicians, if recipient parents are married or if spousal consent has been obtained. Maternal rights are most frequently linked to gestation. Therefore, these laws discourage surrogacy. Outside the statutory regime, paternal genetic connections and preexisting adoption laws determine legal parentage. In this sense, models which appear to be *laissez faire* or remedial may have a distinct chilling effect which can limit access for certain patient groups in nontraditional family situations, particularly unmarried women and women in lesbian relationships.[31] Child status laws should be morally neutral and inclusive to accommodate parental choices comprehensively, particularly as Canadian courts and laws are recognizing a wider concept of family. If the true object of legislation is to discourage certain types of participants, family law provisions within remedial models are not appropriate. They

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[29]Within this model, laws which interfere in medical treatments are not enacted unless a compelling interest is proven to exist. Foreign statutes and Canadian law reform projects demonstrate that protecting the perceived best interests of children born through ARTs is such a compelling interest This is an area of provincial authority and some Canadian provinces have enacted filiation laws for children of ARTs.

[30]As shown in chapters 4 and 5, ART specific enactments employ a narrow view of family and entitlement which may run afoul of human rights laws in general and the *Charter* in particular.

[31]V. Henry, "A Tale of Three Women: A Survey of the Rights and Responsibilities of Unmarried Woman Who Conceive by Alternative Insemination and a Model for Legislative Reform" (1993) 19 Am. J. of L. & Med. 285. See also; A. Capron, "What Rules for Procreation" in C. Mazzioni, ed., *A Legal Framework for Bioethics* (The Hague: Kluwer Law Int., 1998).

do not effectively limit access, instead they create uncertainty for children and the potential for damaging legal battles which punish children for the "transgressions" of their parents and other participants.

OPTION C: The Regulatory Model

A regulatory solution seems most appropriate. Regulatory models are best equipped to balance individual rights and public interests raised by ARTs,[32] to address the conditions under which licit activities occur and to determine the degree to which control is left with the medical profession.[33] In contrast to *laissez faire* models which leave issues first to the parties (predominantly the physicians) and then to incidental judicial resolution, regulatory models can directly and comprehensively address the provision of ARTs, including traditional patient safety and quality of services concerns and broader ethical and societal issues.[34] While all legislation necessarily involves some risk of stifling technology, regulatory measures are less likely than criminal prohibitions to delay or frustrate the clinical introduction of beneficial procedures. Regulatory approaches are a more flexible means to assess the potential benefits and risks in this rapidly evolving medical area than criminal prohibitions. They can anticipate and avoid common or recurrent problems and create a flexible legal mechanism to address changing circumstances and individual cases. Regulatory regimes can create novel legal rights for all participants particularly donors and potential recipients.

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[32]See Nielsen, *supra* note 2 at 40 for a discussion of the basic dilemmas in balancing of individual interests and societal interests.

[33]See Leenen, *supra* note 24 at 81-85.

[34]See R. Roemer, "Health Legislation as a Tool for Public Health and Health Policy" (1998) 49 I.D.H.L. 89.

Developing regulatory legislation to address the ARTs related issues which require some external control is a complex process involving many connected elements, including the nature of the matter at issue, the types of powers to be delegated, the cost, potential liability and expected efficacy.[35] In selecting a basic administrative structure and drafting laws that best achieves the regulatory objectives, care must be taken to account for constitutional limitations. A policy is only as valid as its constituent legislation. A uniform national ARTs policy may be the most economical and practical regulatory solution; however, "[a]s a matter of law, of course, the constitutional arrangements of Canadian federalism cannot be ignored."[36] While s.91 grants the federal government legislative authority over certain aspects of ARTs; it does not authorize Parliament, nor any of its delegates, to enact a comprehensive regulatory scheme governing the delivery of specific medical services such as the system to govern ARTs, genetics, reproductive health and procreation proposed in *Setting Boundaries*. Conversely, provincial enactments which are essentially moral prohibitions are also *ultra vires*. Valid constituent authority is essential for ART legislation, particularly as their controversial nature makes the laws more likely to be challenged by patients, providers, provincial governments and other interested parties. Although a cooperative policy is more difficult to create, it is more likely to be accepted by the participants and to be adjudged lawful.[37] Given these constitutional limitations, three overall regulatory structures seem most feasible: a federal conditional grant system based upon funding authority; a provincial

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[35]See Generally, M. Trebilcock *et al, The Choice of Governing Instrument: A Study Prepared for the Economic Council of Canada* (Ottawa: Minister of Supply and Services Canada, 1982).

[36]P. Healy, *supra* note 14 at 909.

[37]A cooperative framework is more feasible for ARTs than for other industries as the medical profession has many established administrative structures and national advisory and policy making bodies.

regulatory system incorporating national standards; or, a combined system with federal health and safety laws covering reproductive materials and provincial laws for standards of practice and delivery of ARTs. These structures could be supplemented by a federal criminal enactment to single out activities subject to absolute prohibition.

Apart from the constitutional considerations, no set rules dictate how ARTs may be regulated. No legal rules proscribe the distribution of legislative, executive and judicial types of functions amongst the branches of government or statutory delegates. Control may be exercised directly by the legislative branch within the statutes and subordinate legislation; or indirectly through delegation to government departments, professional bodies, independent agencies and courts; or by some combination. No strict rules determine whether specific provisions should be in a statute or in subordinate legislation. Canadian law reform projects and foreign enactments do not point to an obvious format: statutes may be comprehensive or compartmentalized; detailed or general; liberal or restrictive. Given the nature of the issues requiring external regulation,[38] it is reasonable to expect an ARTs statute to include administrative, legislative, and judicial components and a subordinate body to carry out these components.

Following the seven guiding principles, constituent and subordinate legislation must be crafted to achieve policy objectives with minimal interference in personal autonomy over procreation. Overall the legislation should enhance patient choice and minimize conflict. The statute should include the following basic components. It must set out legislative objectives, and a hierarchy

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[38]Patient safety; use of genetic materials; patient access; control over gametes and embryos; surrogacy; experimental use of embryos; records; and, filiation.

of guiding principles.[39] It must create and empower a subordinate authority responsible to carry out the legislative objectives.[40] The statute should address the generally applicable and static components of ARTs such as filiation, consent procedures, surrogacy arrangements and any general prohibitions. On the other hand, issues which must respond to rapid technological developments, and those that involve medical expertise and judgement should be relegated to the more malleable medium of subordinate legislation or left to the discretion of the statutory delegate.[41] For these issues, the act should specify the types of guidelines which must be promulgated; create mechanisms within which moderate consensus can be found; and contain provisions to ensure compliance. The act should include the power to create subordinate laws, set procedural safeguards and limit discretion through a list of relevant and irrelevant factors. In this way the statute provides the obligation and the template to deal with these issues, but not the ultimate resolution. It must also include provisions regarding the accountability of ARTs providers and policy makers as well as a system for dispute resolution that is not necessarily linked to discipline or civil litigation. The next sections will address the

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[39]A system similar to the South Australian legislation seems more suitable for Canada rather than the detailed Victorian statute. The South Australian act gives discretion to a statutory delegate to set the rules and codes to govern ARTs. It establishes guiding principles and imposes relatively few ultimate parameters.

[40]Statutes apply to many people and over a significant time period, rather than to specific individuals or events. They are difficult and time-consuming to change. It is essential to consider the need for future changes regarding sensitive, evolving issues. For an excellent example of the negative effects of rigid statutes even for the predictable and relatively static issue of ultimate storage limits see: R . Edwards & H. Beard, "Debate: Destruction of Cyropreserved Embryos: UK Law Dictated the Destruction of 300 Cyropreserved Human Embryos" (1997) 12 Human Rep. 3 at 4-5.

[41]Subordinate legislation and the delegated discretion are more flexible but they can reduce transparency, accountability and the control of the legislature over the judiciary and professionals. Many key issues involve difficult medical and ethical distinctions such as the assessment of positive and negative eugenics, these distinctions are difficult to make in the "cement of statutory law" P. Healy *supra* note 14 at 913. Subordinate legislation can take many forms including: regulations, ordinances, rules, codes, bylaws, policies and directives. As far as practical all subordinate legislation should take the form of regulations so that safeguards are followed. Regulations are generally made in consultation with affected parties, policies, or directives: see generally, D. Jones & A. deVillars, *Principles of Administrative Law*, 2d ed. (Toronto, Carswell, 1993) at 90-109.

need for a statutory delegate and for statutory provisions regarding the aspects of ARTs warranting external control. Appendix C illustrates the legal framework.

The policy maker or delegated authority and its constituent authority: The nature of ARTs and of regulatory policies in general suggest that some entity will be required to implement, monitor and enforce limits on free choice.[42] Therefore it is essential to identify the decision maker best able to capture the benefits of ARTs and avoid their deleterious effects. The ARTs statute must establish the organisational skeleton of the decision maker including, its governing membership and the limits of its authority, discretion and obligations. Four approaches seem likely: a) exclusive control models where the government implements a monopoly over the provision of ARTs; b) contract compliance models which validate the free will of participants if specified prerequisites are satisfied; c) professional self-regulating models which incorporate professional codes into statutes; or, d) administrative models in which the standards of practice are set and monitored by an independent agency or a government agency.

The fourth option is most appropriate. A government monopoly would obliterate the current private market and would raise *Charter* considerations regarding whether it is the least restrictive means of implementing ARTs policy. A publicly-financed monopoly would also

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[42]All ART specific statutes use administrative bodies to carry out statutory policies. As governments have become more involved in complexities of modern life, they have increasingly turned to delegates for many reasons: someone must actually carry out the policy; the issues are technical; a delegate may have more ability to be flexible especially if obligations are not cast in statutory stone; delegates can be more innovative and can deal with emerging situations and emergencies; they can also be in a more strategical position to deal with politically sensitive issues. See generally D Jones & A deVillars, ibid. at 4-6.

involve the assumption of significant expense and political risk associated with the diversion of scarce health care resources to benefit a relatively small population from other services which are perceived to be more essential or basic. Such unique and preferential treatment could set a precedent for other programs. It creates the opportunity for government to become increasingly involved in reproduction, a marked departure from recent policy on other reproductive fronts. Exclusive control may result in a bureaucratic, rigid and self-serving system which fails to account for interests outside of the agency. Without a coordinating agency, both professional models and contract compliance models suffer the shortcomings outlined of the *laissez faire* model. These models lack coordination, defined responsibility and therefore accountability. They also have no mechanisms to incorporate broader societal and professional input or to provide a mechanism for dispute resolution apart from disciplinary proceedings or civil litigation.

Accordingly a coordinating agency to administer ARTs policy is essential. There is no definitive test to determine whether a government department or an independent agency is a more appropriate policy maker.[43] Given the controversial and personal nature of ARTs, and the extent of external interests, an agency with some degree of independence is probably preferable to a government department (particularly as certain aspects of ARTs involve technical expertise and necessitate the delegation of adjudicative powers.) A coordinating administrative agency is best suited to deal with the collection, maintenance and use of

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[43]See generally, *Regulatory Agencies, A Study Team Report to the Task Force on Program Review* (Ottawa: Minister of Supply and Services, 1986). For a discussion of independence of agencies and tribunals and particularly with respect to the appointment process see Canadian Bar Association Task Force Report, *The Independence of Federal Administrative Tribunals and Agencies in Canada* (Ottawa, the Association, 1990).

confidential information and the resolution of disputes amongst participants. It is better positioned to draw upon the resources of existing medical policy making entities and professional codes[44] while also incorporating other interests and experiences. An independent agency is a more palatable means to receive appointees from across Canada and to resolve politically sensitive issues than a federal government department. Finally, an agency is a necessary component in a licensing or accreditation system. Like other industries ARTs are amenable to control through licensing or registration systems.[45] Compliance and monitoring of compliance have been problematic with self-determined standards. Licensing can improve compliance, but it entails additional powers, bureaucracy and compliance costs. The statute must enable any monitory and revokation powers as well as powers to perform inspections, to subpoena witnesses and to levy costs. While delegates are in charge of their own procedures (subject to the general administrative duty of fairness), the statute should set out procedural safeguards regarding the format and conduct of hearings, the power to levy penalties and appeal procedures.

The statute must set out particulars concerning governance of the agency. If human dignity is to be a paramount principle, then it is essential that the agency have representation from all persons (especially those that much of the treatment is designed to select out of existence.)

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[44]A separate body can regulate the degree of control exercised by the medical profession and allow for input from other sectors. The creation of an independent decision making body does not necessarily imply the exclusion of professional bodies from policy making. Their cooperation and expertise is invaluable with respect to certain issues. Professional participation also reduces the unnecessary duplication and bureaucracy and it strengthens the ability to create enforceable national standards through existing national bodies. See Generally Leenen, *supra* note 24 at 80-81 on the benefits of "legislated self-regulating systems."

[45]The central agency would probably be in a more neutral position than a local subdelegate such as an ethics committee composed of the peers of a particular ART practitioner.

Wide representation can be assured through statutory qualifications such as professional designations in medicine, genetics, law, ethics, or religion; sex; sexual orientation; or, nomination by members of specified groups. To preserve the independence of the agency, members should be appointed for set terms and removed only for cause. A statutory immunity should be provided for members executing their official functions. Independence reduces accountability and transparency so an annual reporting requirement may keep legislators and the public connected to the agency and also aware of novel issues that may necessitate statutory revisions.

Patient Health and Safety: Given the invasive nature of ARTs, the apparent inadequacy of purely professional self-regulation and the serious nature of the decision to seek procreative assistance, statutory assurances through health and safety standards are appropriate and consistent with other health areas. Given the fast pace of development and the need for professional input, this would be an appropriate area for a statutory obligation to create standards and guiding principles. The specifics could be left to the delegated authority who could either adopt established professional standards or modified versions which also reflect other interests. As reproductive materials are often donated or stored with third parties, legislation should also address the screening of donors; the screening, storage and use of reproductive materials; and, the dissemination of information.

Many safety measures are noncontentious. Recipients, practitioners and the public all have a common interest in assuming that providers are adequately skilled; that services are properly performed and supervised and that the reproductive materials are properly screened to

prevent the spread of infectious disease and "serious genetic" impairments. However, in some instances patients' autonomous rights to judge risk and select a course of conduct free from intervention may conflict with the collective interest of patient safety. Disagreement is likely concerning the limits of safety - specifically the division between experimental and therapeutic treatments; the distinction between safety and morality; and, the meaning of serious genetic impairment.[46] These are areas which cannot be left to the profession alone as one of the main criticisms of unregulated ARTs has been the speed at which procedures cross from experimental to therapeutic use and the variety of situations in which procedures are used.[47] Finally, the public health interest in preventing communicable diseases and genetic disorders may also justify provisions which require donors to be notified of any genetic or medical problems that may affect their personal procreative decisions.

Given that the decision to seek procreative assistance is more serious than many other treatment decisions, enhanced disclosure requirements which employ a standard definition of success and nondirective counselling may also be warranted to ensure an appropriate level of disclosure and informed consent. This obligation could be created by a statute which also prescribes consent forms. By law, participants would be required and empowered to address contingencies and to document their own intentions, thereby creating their own rules for dispute resolution, subject to specified statutory limits and statutory default provisions.

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[46]For example, restricting the number of embryos that can be transferred can reduce the chances of successful treatment. The limit may be justified on the basis of safety, but it also includes a moral aspect.

[47]See generally G. White & M. McClure, "Introduction: Introducing Innovation Into Practice: Technical and Ethical Analyses of PGD and ICSI Technologies" (1998) J. of L. Med. & Ethics 5.

Use of Donated Genetic Material: Donor involvement may justify legal intervention over and above traditional safety and screening concerns raised by invasive procedures. Donor involvement is a static element of the ARTs process and is amenable to regulation within a statute or subordinate legislation ensuring minimum conditions for qualification, remuneration, disclosure and confidentiality. For example, an ARTs statute could impose limits on donors based on nonmedical factors, limiting them to living persons, legal adults or adults with certain social characteristics such as a stable marriage, children of their own and spousal consent. The statute could also limit or prohibit financial incentives for donation.

Donors should fully understand and consent to the specific proposed uses of their reproductive materials and should be free to withdraw or alter consent until some other interest overrides their autonomy (such as fertilization). The statute should require documentation of the fact that donors understand long term implications of donation to validate their free will and to minimize the risk of recanting or conflict over resultant children. Statutory rules and safeguards are even more essential if donors are also participants. The law may also be required to control the use of donation as a precondition to access. In such cases providers have a direct conflict of interest and the common law principles such as autonomy may inadequately account for the vulnerability of patient/donors.

Finally, given the legal significance of genetic connections, especially with regard to fatherhood, the ARTs statute should specify that donation severs legal rights of the donor (filiation specifically is dealt with below). The flow of information amongst donors, recipients and offspring is also a contentious issue. As the donor's interests are affected by the use of

their reproductive materials and as the donor's privacy interests may conflict with the child's right to full knowledge of his or her biological origins and *vice versa*, legislation is required to control the flow of information amongst participants.

Patient Access: Patient access is a relatively static issue. While statutes often include access limits, in Canada restrictions based upon personal characteristics of the recipient such as marital status, sexual orientation or age are disguised forms of discrimination and are suspect under *Charter*.[48] Similarly, requirements of parental aptitude and spousal consent may also be difficult to justify. Therefore access is one issue where the *Charter* and judicial recognition of nontraditional family relationships and existing discriminatory practices suggest that statutory provisions are warranted to enhance access and prevent discrimination.

Cost is a significant access issue which should be addressed by statute. If ARTs are provided in the private sector, then the decision to undergo treatment and the specific course of treatment is a matter of personal autonomy, unless it can be established that providing the requested procedure violates human dignity and inappropriately objectifies and commercializes reproduction and human embryos. On the other hand, if ARTs are provided in the public system, restrictions based upon medical need, genetic impairment and chances of success may be justified based on the ethical obligation to spend limited public funds justly and prudently. The Canadian public health system was created to make medical need the

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[48] "Proposals to 'protect children into nonexistence' are really intended to protect society from having to adjust to children born either from unorthodox social arrangements or unaccustomed medical techniques and from having to accommodate novelty in human reproduction." Discrimination is justified on the basis that some ARTs are simply "unnatural": B. Dickens, "News & Views: Reproductive Health Care Policies Around the World: Reproductive Health Care Policies Around the World" (1994) 11 J. Of Asst. Rep & Gen. 327 at 329.

major determinant of access to free care. However, it is notoriously difficult to define "medically necessary" or the limits of "serious genetic impairment or need" in legal instruments so it may be difficult to create legislation to limit access in this manner.[49] Even in the public system, the specific course of treatment is an issue which belongs within the autonomy of the patient. Access is further complicated as some ARTs involve patients who have no personal medical need for treatment. They are only involved due to the infertility or the needs of others. If the patient is intended to be the custodial parent, then there is an indirect benefit to treatment. If the patient is a surrogate, then there is no such personal benefit. These differences may be adequate to override the reluctance to interfere in patient/physician relationships and justify statutory safeguards or limits to protect the patient against undue harm or coercion.

Physical Separation of Gametes, Embryos and Their Intended Recipients: Separation is another static element of ARTs amenable to statutory or regulatory control. The deliberate separation of physical custody of reproductive materials or embryos from their human sources creates the potential for disputes over their care, control, custody or ultimate use. The law applicable to these disputes is uncertain due to the murky status of human embryos and the unresolved hierarchy of biological, custodial, contractual and social ties. The statute can set limits on the use of embryos and within those limits ensure that donors deal with the issues themselves through a mandatory pretreatment written documentation of the acceptable future

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[49]E.G. consider the differences between a married couple where the husband is infertile and the fertile wife elects to undergo IVF with ICSI instead of less costly, less risky and more successful AI options; a mother who acts as a surrogate for a sterile daughter; a lesbian couple seeking AI; and a homosexual male who commissions a surrogate to gestate an embryo created from a donated ovum and his own sperm.

uses of materials in the event of certain contingencies. In the event that theparticipants fail to address an issue, a certain and just resolution can be guaranteed through default statutory rules covering: a hierarchy of competing claims, the expiry of storage limits, death or incapacity of the parties, divorce, disagreement or abandonment of treatment. If absolute limits are desired (such as ultimate limits on use of embryos, and storage agreement terms about remuneration for safekeeping and default), then these should be included in the statute

Separation of Gestation and Parenting (Surrogacy): Surrogacy is a well defined and static concept amenable to statutory control. Regulation of this ART is warranted for the many reasons described above. If surrogacy is to be banned, the ban should be accomplished through a public statute.[50] If surrogacy is to be allowed, then the statute should ensure certain outcomes. For example, mandatory licensing of surrogates and providers and detailed consent procedures involving the physician, the surrogate and the recipient couple could account for imbalances in power. The ARTs statute should also set certain mandatory contract terms and certain inalienable rights including whether or not the surrogate would possess the right to renege on the agreement, subject to the genetic parents right of access.[51] Finally, the statute must address the transfer of legal parentage to overrule existing filiation laws in a manner which respects the privacy of the participants, but makes them responsible for their

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[50]This could also be accomplished as it is in many other countries by statutory declaration that agreements are unenforceable, invalid or void, or by prohibition on licensing the provision or enablement of surrogacy.

[51]Other mandatory contract provisions would address: consent during pregnancy; submission to reasonable medical evaluation and treatment and prenatal care; the relinquishment of parental rights; obligation to assume custody and full parental rights and responsibility for the child regardless of any impairment; and, remuneration and recoverable expenses. See the American provisions outlined in chapter 4. See generally C. Chisick & D. Bacus, "Not Just a Human Incubator: Legal Problems in Gestational Surrogate Motherhood" (1997) 25 Man. L. J. 49.

reproductive choices. Once again statutory rules which restrict access, particularly those which relate to the couples need for surrogacy and nonmedical issues, raise *Charter* issues.

Therapeutic Treatment and Experimental use of Embryos: Embryonic experimentation is less directly related to therapeutic procreative assistance and may belong in statutes that address genetics, the use of aborted fetuses and restrictions on experimentation with human subjects in general. Therapeutic treatment of embryos and the distinction between therapeutic and experimental treatment are subject to the same considerations outlined above under patient safety. If experimental use is permitted, then at a minimum the statute must recognize that the embryo is an entity deserving respectful treatment. In addition, some absolute statutory limits may be warranted such as: limits on the purposes of experimentation, developmental limits to prevent suffering; and, the requirement that proposed experiments be limited to procedures that cannot otherwise be performed.

Genetic Testing and Manipulation: In this area preimplantation genetic diagnosis and gene therapy must be distinguished. Currently, gene therapy remains experimental and is subject to the comments above on experimentation and the need for subordinate legislation to define the line between therapy and experimentation. Preimplantation genetic diagnosis is the screening of *ex utero* embryos for specific conditions. While it may be used to simply provide information; it is also the basis for selecting one embryo over another or for discarding embryos just as it is the basis for the abortion of *in utero* foetuses. The central issue is whether there should be limits upon the characteristics or conditions of embryos that can be disclosed to patients. While extreme cases may seem obvious, it can be very difficult to

determine what constitutes a genetic impairment, disease, propensity or other characteristic in need of correction or elimination. Sex selection is often cited as an example of information which should not be supplied. This is an extremely contentious issue that squarely raises the moral value of embryos, the autonomy of participants and the broader meaning of human dignity.[52] The ability to detect, control and eliminate genetic characteristics of human embryos tends to commodify procreation and a child of one's own. This controversial issue is not amenable to statutory intervention as it requires medical and personal judgement, it directly, uniquely and profoundly affects parents interests and involves rapidly developing areas of science. If it is determined that these techniques raise broader concerns regarding the value of all types of human life and human dignity in relation to genetic discrimination and eugenics in general, then some limits on testing should be created through subordinate legislation. The statute would only empower the policy maker to create a list of allowable tests or conversely to prohibit testing for certain procedures. The statute may also include the proviso that the preimplantation testing policy take account of the available *in vivo* prenatal tests.

Long Term Maintenance of Records and Identifying Information: If the purpose of the statute is to regulate therapeutic and experimental procedures and to set safety standards, then there will have to be a flow of information between standard setters and providers. The collection, maintenance and use of linked or linkable records raises issues of confidentiality. The flow of information is a controversial issue; but it is a static issue that, like surrogacy, may be addressed universally in a statute. The content and consequences of information

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[52]See generally J. Botkin, "Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis" (1998) J. of L. Med. & Ethics 17.

changes with time, but the flow of information does not. While some aspects of confidentiality are covered information and privacy acts or legislation concerning hospital records, coverage may not exist in all provinces and may not adequately address this issue. Therefore, the ARTs statute must address the access and exchange of information, the wrongful disclosure of information and particularly "look back" procedures, mechanisms to link donors and offspring and the rights of offspring to know their genetic roots.

Filiation: All children of ARTs need certainty regarding their legal status. Statutory provisions are required to realign social and legal parentage in the child's interests. For the reasons outlined above, the statute should create an inclusive means to regularize social situations with the least inconvenience and most privacy for the family. The statute should provide that donation severs legal parenthood. Given that the law transfers the burden and benefits of parentage, consent or acquiescence should be a condition of parental status. This also recognizes that the embryo is not a legal entity and that the fathers' choice not to be a father is not in competition with the mothers' right to physical autonomy. These laws should also address parental rights and the relative legal significance of gestation and genetics in the event of certain contingencies such as an error on the part of the provider resulting in unauthorized fertilization of gametes or gestation of the wrong embryo. While filiation may be addressed in an ART specific act, it is really a separate issue involving the legal relationship amongst resultant children and their parents that seems more aptly located in provincial family law enactments.

D. Conclusion

The provision of ARTs brings ethics and science into direct conflict. It raises issues connected to the meaning of procreation and the value of human life, in all its forms and imperfections. ARTs are highly controversial and sensitive. They involve the appropriateness of medical and legal interventions in a private sphere central to human existence. While the decision to seek assistance in reproduction is highly personal, the personal and professional choices of users and providers can have profound normative and financial impacts for other groups, and for the entire society over the long term. ARTs raise traditional regulatory issues about patient safety. They also involve personal and ethical considerations including individual motivations for seeking a child of one's own and the subjective meaning of a child of one's own. Views on these issues are as unique and diverse as the individual participants. ARTs policy must address these issues as well as difficult questions such as what elements of personal freedom should be restricted for broader objectives, who should determine the value of genetic patrimony, the potential for human life embodied in embryos or human life in all its forms.

The unique characteristics of ARTs (particularly the externalities not raised by other treatment transactions), together with the practical inequities and inconsistencies revealed by the reform commissions and the existing jurisprudence suggest that some form of ART specific legislation is warranted. However, they do not point to a single legislative solution. A regulatory model is the best means of capturing the benefits of ARTs while avoiding misuse and conflict. The statute should address the more static, generally applicable and absolute issues directly and then create a regulatory mechanism equipt to deal with the more dynamic, context dependent and technical aspects.

Creating legislation to dictate highly personal choices and autonomy and privacy is always difficult, but the process is confounded by the plurality of views, norms, and cultural experiences of Canadians, by the constitution and by the rights-based concept of law. While these complications make the task more difficult, an attempt should be made. A child of one's own is a truly amazing prospect - society cannot usurp the reproductive autonomy of patients and proscribe their eligibility and their course of treatment in relation to this prospect, but neither can it abandon patients in the waiting room.

> Science and technology are advancing rapidly. If democracy is to be more than a myth and a shibboleth in the age of mature science and technology and more than a triannual visit to a polling booth, we need a new institutional response. Otherwise we must simply resign ourselves to being taken where the scientists and the technologies' imagination leads. That path may involve nothing less that the demise of the rule of law as we know it. It is for our society to decide whether there is an alternative or whether the dilemmas posed by modern science and technology, particularly in the field of bioethics, are just too painful, technical, complicated, sensitive and controversial for our institutions of government.[53]

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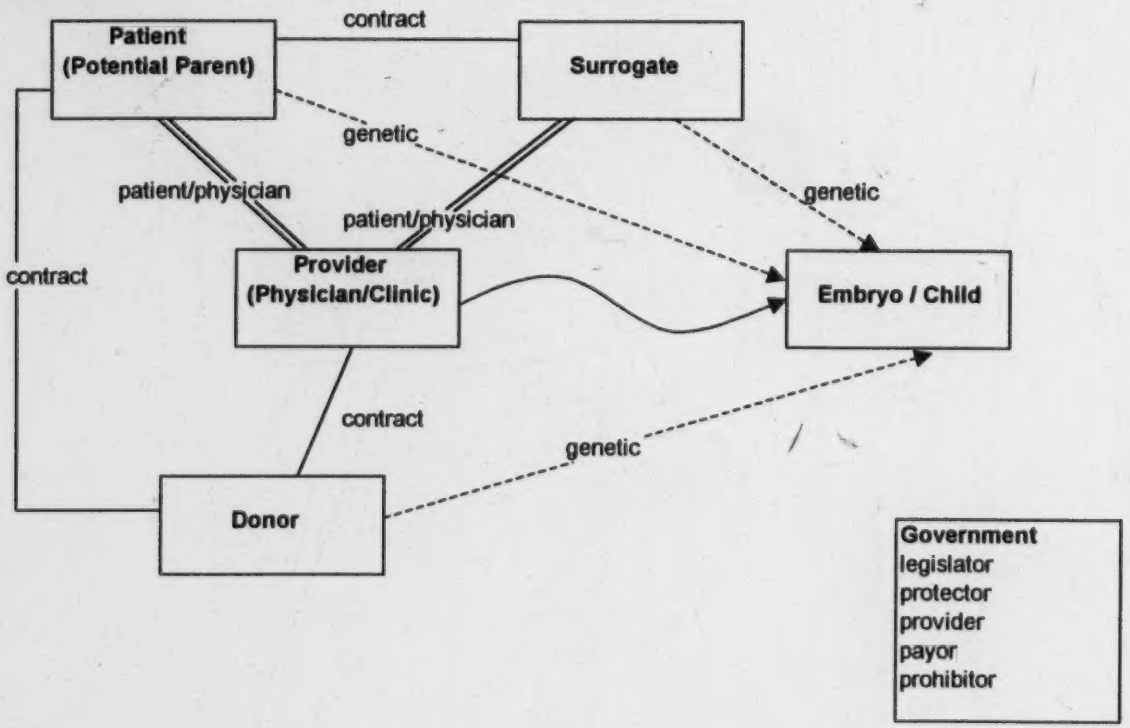
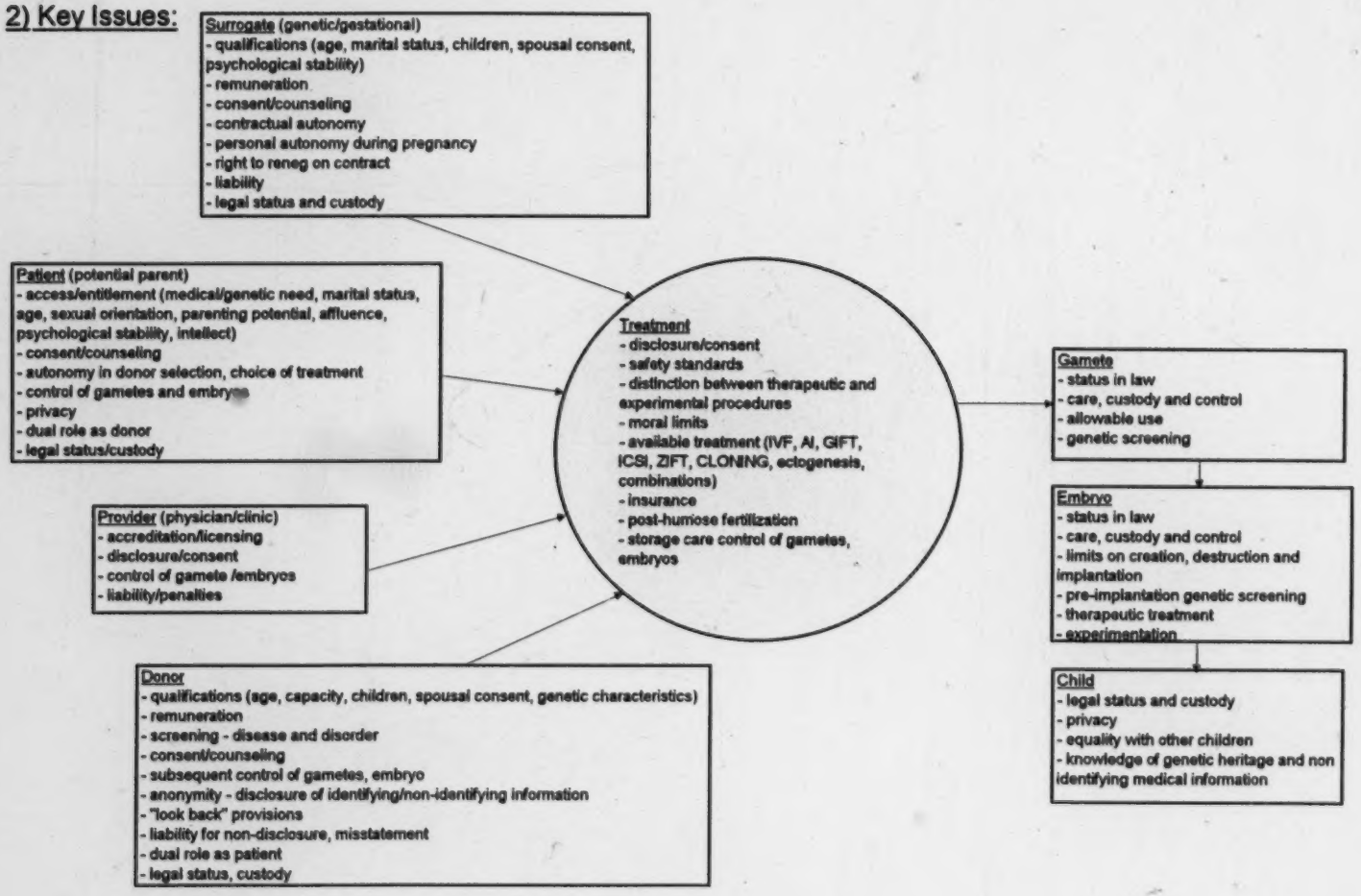
[53]L. Nielsen "Legal Consensus and Divergence in Europe in the Area of Assisted Conception - Room for Harmonisation? D. Evans, ed., *Creating the Child* (The Hague: Kluwer Law International, 1996) 305 at 320.

Appendix A: Elements of New Reproductive Technology Transactions

1) Relationships:



2) Key Issues:


Surrogate (genetic/gestational)
- qualifications (age, marital status, children, spousal consent, psychological stability)
- remuneration
- consent/counseling
- contractual autonomy
- personal autonomy during pregnancy
- right to reneg on contract
- liability
- legal status and custody
Patient (potential parent)
- access/entitlement (medical/genetic need, marital status, age, sexual orientation, parenting potential, affluence, psychological stability, intellect)
- consent/counseling
- autonomy in donor selection, choice of treatment
- control of gametes and embryos
- privacy
- dual role as donor
- legal status/custody
Provider (physician/clinic)
- accreditation/licensing
- disclosure/consent
- control of gamete /embryos
- liability/penalties
Donor
- qualifications (age, capacity, children, spousal consent, genetic characteristics)
- remuneration
- screening - disease and disorder
- consent/counseling
- subsequent control of gametes, embryo
- anonymity - disclosure of identifying/non-identifying information
- "look back" provisions
- liability for non-disclosure, misstatement
- dual role as patient
- legal status, custody
Treatment
- disclosure/consent
- safety standards
- distinction between therapeutic and experimental procedures
- moral limits
- available treatment (IVF, AI, GIFT, ICSI, ZIFT, CLONING, ectogenesis, combinations)
- insurance
- post-humose fertilization
- storage care control of gametes, embryos
Gamete
- status in law
- care, custody and control
- allowable use
- genetic screening
Embryo
- status in law
- care, custody and control
- limits on creation, destruction and implantation
- pre-implantation genetic screening
- therapeutic treatment
- experimentation
Child
- legal status and custody
- privacy
- equality with other children
- knowledge of genetic heritage and non identifying medical information

Appendix B: Canadian ARTs Specific Legislation

NEWFOUNDLAND: *The Children's Law Act* R.S.N.1990, c.13

12.(1) In this section "artificial insemination" includes the fertilization by a man's semen of a woman's ovum outside of her uterus and subsequent implantation of the fertilized ovum in her.

(2) A man whose semen was used to artificially inseminate a woman is in law the father of the resulting child if he was married to or cohabiting with the woman at the time she is inseminated even if his semen was mixed with the semen of another man.

(3) A man who is married to a woman at the time she is artificially inseminated solely with the semen of another man shall be considered in law to be the father of the resulting child if he consents in advance to the insemination.

(4) A man who is not married to a woman with whom he is cohabiting at the time she is artificially inseminated solely with the semen of another man shall be considered in law to be the father of the resulting child if he consents in advance to the insemination, unless it is proved that he refused to consent to assume the responsibilities of parenthood.

(5) Notwithstanding a married or cohabiting man's failure to consent to the insemination or consent to assume the responsibilities of parenthood under subsection (3) or (4), he shall be considered in law to be the father of the resulting child if he has demonstrated a settled intention to treat the child as his child unless it is proved he did not know that the child resulted from artificial insemination.

(6) A man whose semen is used to artificially inseminate a woman to whom he is not married or with whom is not cohabiting at the time of the insemination is not in law the father of the resulting child.

QUEBEC: *Civil Code*

Art. 523 Paternal filiation and maternal filiation are proved by the act of birth, regardless of the circumstances of the child's birth.

In the absence of an act of birth, uninterrupted possession of status is sufficient.

Art. 538 Participation in the parental project of another person by way of a contribution of genetic material to medically assisted procreation does not allow the creation of any bond of filiation between the contributor and the child born of that

procreation.

Art 539 No person may contest the filiation of a child on grounds relating to his medically assisted procreation, and no claim to another status is admissible from the child.

However, the husband of the mother may disavow the child or contest acknowledgement if he did not give consent to medically assisted procreation or if he proves that the child was born of such procreation.

Art 540 A person who, after consenting to medically assisted procreation, does not acknowledge the child born of such procreation is responsible to the child and to the mother of the child.

Art. 541 Procreation or gestating agreements on behalf of another person are absolutely null.

Art 542 Nominative information relating to the medically assisted procreation of a child is confidential.

However, where serious injury could be caused to the health of a person born of such procreation or of any of his descendants if he were deprived of the information he requires, the court may allow such information to be transmitted confidentially to the medical authorities concerned. A descendant of such a person may also avail himself of this right if the fact that he is deprived of the information he requires could be the cause of serious injury to his health or to the health of any of his close relatives.

Canada, Uniform Law *Conference: Uniform Child Status Act*

11. In sections 11.1 to 11.6, "assisted conception' means a conception resulting
a) by means other than sexual intercourse, or
b) by removal and implantation of an embryo after sexual intercourse.

11.1 No person other than a duly qualified medical practitioner shall carry out a procedure on a woman that results in or is intended to result in an assisted conception.

11.2 Notwithstanding section 6(3), for a child born before or after this section comes into force as a result of an assisted conception, a presumption of paternity pursuant to section 9 may be rebutted only by proof that

a) the presumed father
(i) is not the genetic father of the child, and
(ii) did not consent, or before the conception withdrew his consent, to be the

father of any child born as a result of the assisted conception; or

b) where the sperm of the presumed father was used in the assisted conception,
   (i) he did not consent, or before conception withdrew his consent, to be the father of any child born as a result of the assisted conception, and
   (ii) the child was not conceived as a result of sexual intercourse between the mother and him.

11.3 A Woman who gives birth to a child before or after the coming into force of this section is deemed to be the mother of the child whether the woman is or is not the genetic mother of the child.

11.4 (1) A woman whose egg is used in an assisted conception and who does not give birth to the child conceived using her egg is deemed not to be the mother of the child.

(2) A man whose sperm is used in an assisted conception and who is not presumed to be the father of a child pursuant to section 9 is deemed not to be the father of the child.

11.5 (1) No person shall, directly or indirectly, buy, sell or otherwise deal in human eggs, sperm or embryos.

(2) A person who contravenes this section is guilty of an offence and liable on summary conviction to a fine of not more than $100,000, to imprisonment for not more than one year or to both.

(3) This section does not prohibit a person from giving or receiving reimbursement for reasonable expense necessarily incurred in donating her own eggs or his own sperm.

11.6 (1) Every duly qualified medical practitioner who carries out procedures that are intended to result in an assisted conception shall maintain, in the form and manner prescribed in the regulations, records indicating the donor and recipient of every egg or sperm used in the assisted conception procedures.

(2) Every duly qualified medical practitioner who carries out procedures that are intended to result in assisted conceptions shall submit information within the knowledge of the practitioner with respect to
   a) assisted conceptions that result from procedures carried out by the practitioner,
   b) births resulting from assisted conceptions that result from procedures carried out by the practitioner, and
   c) procedures carried out by the practitioner that are intended to result in assisted conception, where the practitioner does not know whether conception was or was not achieved.

(3) Every duly qualified medical partitioner shall submit information within the knowledge of the practitioner with respect to births of children delivered by the practitioner that result form assisted conceptions.

(4) The information mentioned in subsection (2) or (3) is to be submitted to the agency designated in the regulations in the form and manner and at the times prescribed in the regulations.

(5) The agency that receives information pursuant to subsection (4)
   a) shall maintain a permanent registry of the information, and
   b) shall not disclose or communicate the information except in accordance with the terms and conditions prescribed in the regulations.

(6) The Lieutenant Governor in Council [or other regulation making authority in the jurisdiction] may make regulations prescribing any matter or thing that is required or authorized by this section to be prescribed in the regulations.

Canada: Bill C-47, *Human Reproduction and Genetic Technologies Act*, 2nd sess., 35th Parl., 1996

An Act respecting human reproductive technologies and commercial transactions relating to human reproduction.

WHEREAS the Parliament of Canada is gravely concerned about the significant threat to human dignity, the risks to human health and safety, both known and unknown, and other serious social and ethical issues posed by certain reproductive and genetic technologies;

WHEREAS the Parliament of Canada acknowledges the health and ethical dangers inherent in the commercialisation of human reproduction, including the sale of reproductive materials, the trade in reproductive capacities of women and the exploitation of women and children for commercial ends;

AND WHEREAS the Parliament of Canada recognizes the need for measures to protect and promote the best interests of children affected by such technologies and transactions;

NOW, THEREFORE, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

1. This Act may be cited as the *Human Reproductive and Genetic Technologies Act.*

2. The definitions in this section apply in this Act.

"donor", in relation to ova or sperm, means the person who produces the ova or sperm, whether or not for purposes of donation.

"embryo" means a human organism during the period of its development beginning on the fifteenth day and ending on the fifty-sixth day following fertilization.

"foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilization and ending at birth.

"Minister" means the Minister of Health.

"ovum" means a human ovum.

"sperm" means a human sperm.

"zygote" means a human organism during the first fourteen days of its development following fertilization, excluding any time spent in a frozen state.

3. The objects of this Act are

a) to protect the health and safety of Canadians in the use of human reproductive materials for assisted reproduction, other medical procedures and medical research;

b) to ensure the appropriate treatment of human reproductive materials outside the body in recognition of their potential to form human life; and

c) to protect the dignity of all persons, in particular children and women, in relation to uses of human reproductive materials.

4. (1) No person shall knowingly

a) manipulate an ovum, zygote or embryo for the purpose of producing a zygote or embryo that contains the same genetic information as a living or deceased human being or a zygote, embryo or foetus, or implant in a woman a zygote or embryo so produced;

b) cause the fertilization of a human ovum by sperm of an animal or the fertilization of an animal ovum by human sperm, for the purpose of producing a zygote that is capable of differentiation;

c) fuse human and animal zygotes or embryos;

d) implant a human embryo in an animal or an animal embryo in a woman;

e) alter the genetic structure of an ovum, sperm, zygote or embryo if the altered structure is capable of transmission to a subsequent generation;

f) retrieve an ovum or sperm from a foetus or cadaver with the intention

   I) that the ovum mature outside the human body, be fertilized or be implanted in a woman, or

   ii) that the sperm be used to fertilize an ovum

g) cause an ovum or sperm retrieved from a foetus or cadaver to mature outside the human body, or

   I) cause the fertilization of such an ovum, or fertilization of an ovum by such sperm, or

   ii) implant in a woman such an ovum, or an ovum fertilized by such sperm;

h) use any medical procedure for the purpose of ensuring, or increasing the probability,

that a zygote or embryo will be of a particular sex, except for reasons related to the health of the zygote or embryo;

I) use any diagnostic procedure for the purpose of ascertaining the sex of procedure for the purpose of ascertaining the sex of a zygote, embryo or foetus, except for reasons related to its health;

j) maintain an embyro outside the human body; or

k) cause the fertilization of an ovum outside the human body for purposes of research.

(2) No person shall offer to carry out any procedure prohibited by subsection (1).

(3) No person shall offer consideration to any person for carrying out any procedure prohibited by subsection (1).

5. (1) No person shall give or offer consideration to a woman to act as a surrogate mother.

(2) No person shall give or offer consideration to another person to obtain the services of a surrogate mother.

(3) No person, other than the surrogate mother, shall arrange or offer to arrange, for consideration, the services of a surrogate mother.

(4) For the purposes of this section, a surrogate mother is a woman who carries a child, conceived from an ovum, sperm or zygote provided by a donor, with the intention of surrendering the child after birth.

6. (1) No person shall sell, purchase, barter or exchange or offer to sell, purchase, barter or exchange, any ovum, sperm, zygote, embryo or foetus.

(2) Subsection (1) does not apply in respect of the reimbursement of expenses incurred in the collection, storage or distribution of ova or sperm, except any such expenses incurred by their donor.

7. (1) No person shall use any ovum for the purpose of research, donation, maturation, fertilization or implantation in a woman unless the donor of the ovum has consented to its use for that purpose.

(2) No person shall use any sperm for the purpose of research, donation, maturation, fertilization or insemination of a woman unless the donor of the sperm has consented to its use for that purpose.

(3) No person shall use a zygote or embryo for the purpose of research or implantation in a woman unless the donors of the ovum and sperm that produced it have consented to its use for that purpose.

(4) Subsection (2) does not apply in respect of the use of sperm for purposes of

identification or prosecution in relation to an offence under the *Criminal Code*.

8. Any person who contravenes any of sections 4 to 7 is guilty of an offence and

a) is liable, on summary conviction, to a fine not exceeding $250,000 or imprisonment for a term not exceeding four years or to both; or
b) is liable, on conviction on indictment, to a fine not exceeding $500,000 or imprisonment for a term not exceeding ten years or to both.

9. The Minister may notify any interested authority established under the laws of Canada or a province of the identity of a person charged with an offence under this Act.

10. A court that imposes a fine or term of imprisonment on a person in respect of an offence under this Act may

a) order any forfeiture and disposition of anything by means of which the offence was committed; or
b) on application by the Minister, enjoin the person from engaging in any activity that, in the court's opinion, may lead to the commission of an offence under this Act.

11. A prosecution for an offence under this Act may not be instituted unless it is consented to by or on behalf of the Attorney General of Canada.

12. The Minister may designate any person or any class of persons to be an inspector or an analyst for the purposes of this Act, and sections 22 to 29 and 35 of the *Food and Drugs Act* apply to those persons, with such modifications as the circumstances require.

13. The Governor in Council may make regulations for carrying out the purposes and provisions of this Act.

14. This Act or any of its provisions comes into force on a day or days to be fixed by order of the Governor in Council.

Canada: Processing and Distribution of Semen for Assisted Conception Regulations SOR 96/254.

1. The definitions in this section apply in these Regulations.

"assisted conception" means a reproductive technique performed on a woman for the purpose of conception, using semen from a donor who is not her spouse or sexual partner.

"container" means a straw, vial, ampule or similar receptacle used to contain semen, that is in direct contact with the semen.

"Director" means the Assistant Deputy Minister, Health Protection Branch, Department of National Health and Welfare.

"Guidelines" means the *Guidelines for Therapeutic Donor Insemination 1992:1993*, as amended from time to time, published by the Canadian Fertility and Andrology Society, Montreal, 1993.

"process", in respect of semen, means to collect, test, prepare, preserve, label and store the semen for use in assisted conception, and includes the measures referred to in paragraph 9(*a*).

2. These Regulations apply only in respect of semen that is used or intended for use in assisted conception.

3. (1) The provisions of Part A of the *Food and Drug Regulations* in respect of the importing, labelling and packaging of drugs do not apply in respect of semen.

(2) Part C of the *Food and Drug Regulations* does not apply in respect of semen.

4. (1) No person shall distribute semen unless

a) the semen has been processed in accordance with sections 9 to 11; and
b) after the semen has been quarantined for a minimum of six months,
   I) it is determined that the donor is still not within a group set out in the Guidelines under the heading "Exclusions", and
   ii) the donor is re-tested as set out in the Guidelines under the heading "Repeat Screening & Quarantine" and the results of the tests are negative

(2) No person shall distribute semen that is required to be quarantined or destroyed under paragraph 9(b) or (c), 15(1)(a), 16(2)(c) or (d) or subsection 17(1) or (3).

5. No person shall import semen for distribution unless
a) it meets the requirements set out in subsection 4(1); and
b) the outer shipping container in which the semen is transported displays clearly, on the outside surface of that container,
   I) the name and business address of the processor, and
   ii) a declaration, signed by the processor or an authorized agent of the processor, certifying that the semen has been processed in accordance with these Regulations and quarantined for a minimum of six months.

6. (1) Every person who processes or imports, or intends to process or import, semen for distribution shall give written notice to the Director of the processing or importing
a) on or before August 1, 1996, if they began processing or importing semen before June 1, 1996; or
b) at least 10 days before the date on which they begin processing or importing semen, if that date is on or after June 1, 1996.

(2) The notice shall be signed and dated by the processor or importer, or an authorized agent of the processor or importer, and shall include

a) the name and business address of the processor or importer;

b) if the notice is signed by an authorized agent, the name and title of the agent; and

c) the date on which the processor or importer began, or intends to begin, processing or importing semen.

7. A processor or importer of semen shall provide any additional information that the Director may in writing request, on or before the date set out in the request, in order to establish that the semen was processed in accordance with sections 9 to 11.

8. (1) Every person shall, within 90 days after they have stopped processing or importing semen, give written notice to the Director indicating that they have stopped processing or importing semen.

(2) The notice shall be signed and dated by the processor or importer, or an authorized agent of the processor or importer, and shall include

a) the name and business address of the processor or importer;

b) if the notice is signed by an authorized agent, the name and title of the agent; and

c) the date on which the processor or importer stopped processing or importing semen.

9. Every person who processes semen for distribution shall

a) take the measures set out in the Guidelines under the headings "Exclusions", "Work-up", "Repeat Screening & Quarantine" and "Semen Microbiology";

b) where a donor is rejected as a result of measures taken in accordance with paragraph (a),

I) if none of the donor's semen, whenever donated, has been distributed, destroy all of the donor's semen that is in the processor's possession, or

ii) if some of the donor's semen, whenever donated, has been distributed, take the measures set out in sections 15 to 18; and

c) where the white blood cells in a test sample of the donor's semen are greater than 10^6/mL, destroy all semen provided by the donor on the same date as that on which the semen in the test sample was provided.

10. Every person who processes semen for distribution shall ensure that all surfaces, containers and other objects that come in contact with the semen during processing

a) are sterile or are clean and disposable; and

b) are of a material and type that provide adequate protection against contamination of the semen.

11. (1) Every person who processes semen for distribution shall

a) mark on each container of he semen, in indelible ink, an identification code that enables the semen to be linked to the donor and to the date of the donation; and

b) distribute with each container of the semen the processor's name and business address.

(2) Every person who distributes semen shall ensure that each container of the semen is marked with, and accompanied by, the information described in subsection (1).

12. (1) Every person who processes semen for distribution shall maintain the following records in respect of each donor:

a) the date of each donation and the results of the tests, screening and monitoring performed in respect of the donor, including, if necessary, an interpretation of the results;

b) in respect of each donation, the identification code marked on each container of the donor's semen, and the number of containers having that identification code;

c) if the processor is a physician who uses the donor's semen in the performance of assisted conception, the identification code marked on the container of semen and a means to identify the woman on whom the assisted conception was performed;

d) if a container of the donor's semen is distributed for further distribution, the name and business address of the person who received the container and the identification code marked on it; and

e) in respect of each container of the donor's semen that the processor destroys, the identification code marked on it and the reason for its destruction.

(2) Every person who processes semen for distribution shall establish and maintain written standard operating procedures to be followed in

a) processing semen; and

b) tracing semen in accordance with sections 15 to 18.

13. Every person who distributes semen processed by another person shall keep the following records in respect of each container of that semen:

a) the name and business address of the processor and the identification code marked on the container;

b) if the distributor received the container of semen from a person other than the processor, the name and business address of that person;

c) evidence that the semen was processed in accordance with these Regulations;

d) if the distributor is a physician who uses the semen in the performance of assisted conception, a means to identify the woman on whom the assisted conception was performed;

e) if the container of semen is distributed for further distribution, the name and business address of the person who received it;

f) in respect of each container of semen that the distributor destroys, the reason for its destruction; and

g) in respect of each container of semen that the processor collects under paragraph 16(2)(c), the date of its collection.

14. Where a physician who performed assisted conception on a woman has reasonable grounds to believe that an infectious agent was transmitted to the woman through semen used in the performance of the assisted conception, the physician shall, without delay,

a) stop the distribution of all containers of semen in the physician's possession having the same identification codes as that of the semen used for the assisted conception; and

b) provide a written report to each processor of the semen

I) advising that semen that they processed may be contaminated by an infectious agent and naming the agent, and

ii) specifying the identification codes marked on the containers of that semen.

15. (1) Where a processor receives a report under paragraph 14(b), or otherwise has reasonable grounds to believe that semen that the processor processed and distributed may be contaminated by an infectious agent, the processor shall, without delay,

a) identify the donors of the semen and quarantine all semen from those donors that is in the processor's possession;

b) use all reasonable means to identify, and locate the business address of, each person who received for further distribution semen obtained from any of those donors;

c) give to each of the following persons a written notice specifying the identification codes marked on the containers of the semen believed to be contaminated, naming the infectious agent and indicating that the semen must be quarantined pending the completion of an investigation or must be destroyed, namely

I) any person to whom the processor distributed, for further distribution, containers of semen having the identification codes specified in the notice, and

ii) any other person who the processor believes received, for further distribution, containers of that semen;

d) notify the donors of the semen in writing that an investigation is being conducted to determine whether semen that they donated is contaminated by an infectious agent, and naming the agent, and

e) conduct an investigation to determine whether any of the semen provided by those donors is contaminated by an infectious agent.

(2) Every person who distributed semen that is subject to investigation under paragraph (1)(e) shall, at the request of the processor conducting the investigation, provide the name and business address of every person to whom the person distributed the semen for further distribution.

(3) Every processor who conducts and investigation shall provide the Director with the following information at the following times.

a) within three days after the start of the investigation, the name of the infectious agent with which the semen is believed to be contaminated, the number of donors who donated semen that is believed to be contaminated and the number of containers of semen attributable to each donor; and

b) every 30 days after the start of the investigation, until the final report is provided, an update on the progress made in tracing the semen, including information as to the number of containers used, recovered, quarantined or destroyed, and the number of persons contacted.

16. (1) Where the results of the investigation demonstrate that all or some of the semen is

not contaminated by an infectious agent, the processor

a) shall prepare a list specifying the identification codes marked on the containers of the semen that is not contaminated;

b) shall notify each person referred to in paragraph 15(1)(c), in writing, that the containers having the identification codes specified in the list may be distributed; and

c) may distribute the containers in the processor's possession that have the identification codes specified in the list.

(2) Where the results of the investigation demonstrate that all or some of the semen is contaminated by an infectious agent, or the results are inconclusive as to whether the semen is contaminated, the processor shall

a) prepare a list specifying the identification codes marked on the containers of the semen that is or may be contaminated;

b) notify each person referred to in paragraph 15(1)(c), in writing, that all quarantined containers having the identification codes specified in the list must be collected by the processor;

c) collect and destroy the containers of semen referred to in paragraph(b); and

d) destroy the containers of semen in quarantine under paragraph 15(1)(a) that have the identification codes specified in the list.

17. (1) Every person who receives a notice of an investigation from a processor shall

a) quarantine all containers of semen having the identification codes referred to in the notice until the person receives a further notice under section 16; or

b) destroy those containers of semen.

(2) Where the person receives a notice referred to in paragraph 16(1)(b), the person may distribute the semen specified in the notice.

(3) Where the person receives a notice referred to in paragraph 16(2)(b), the person shall

a) keep in quarantine all containers of the semen having the identification codes referred to in the notice until they are collected by the processor, or destroy them; and

b) provide a written report to the processor as soon as possible indicating, for each identification code referred to in the notice, the number of containers received by the person and the number that were distributed or destroyed.

18. Every processor who conducts an investigation under paragraph 15(1)(e) shall, on completion of the investigation,

a) provide the Director with a detailed report setting out the results of the investigation, including, where the processor is required to collect and destroy semen, the disposition of all containers of that semen; and

b) notify in writing the donors of the semen of the results of the investigation.

19. These Regulations come into force on June 1, 1996.

Appendix C: Regulatory Policy Formulation

Step 1: Identifying issues that warrant external regulation:

Societal

Issues that raise broader societal interests to be governed by law
(statutes and subordinate legislation guides and limit individual choice and decision making).

Professional

Issues to be governed by the profession collectively
(guidelines and codes of conduct limit individual choice and decision making).

Individual

Issues to be decided autonomously by the individual participants within patient/physician and other relationships.

Step 2: Constructing a legal control mechanism

Issues to be decided by the legislator
(constituent/enabling statute and regulations)
Static issues, issues of general application

-Objectives of the law
- Hierarchy of guiding principles
- Absolute prohibitions
- Filiation and custody
- Surrogacy (ban, mandatory contract terms)
- Cost, insurance coverage
- Access
- Donor qualifications
- Consent and counseling requirements
- Confidentiality, flow of information
- Hierarchy of claims to gametes / embryos
- Default provisions (in the event of contingencies such as death, divorce, incapacity, abandonment of project, passage of time)
- General limits on financial incentives
- General limits on experimental use, genetic therapy and preimplantation genetic testing
- Constitution of delegated authority (including membership, governance, constituent authority, powers and limits on discretion, and procedural requirements, immunity, reporting obligations, and appeal procedures)

Issues to be decided by the statutory delegate in accordance with the provisions of the constituent / enabling statute and regulations
(Subordinate legislation and administrative discretion)
Dynamic issues, issues which require medical expertise, issues applicable to specific individuals only.

- safety standards and practice guidelines
- forms
- licensing
- monitoring
- records collection, maintenance and use
- dispute resolution (for licensees and patients)
- distinction between therapeutic and experimental procedures
- limits on preimplantation genetic testing

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